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Chloroneb: Pesticide Registration Standards

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Office of
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Pesticides

EPA

1, 4-dichloro-2,5 -dimethoxybenzene

Chloroneb

Pesticide Registration Standard

EPA/SPRD- 80/510

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CHLORONEB

Pesticide Registration Standard

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Chapter 1

HOW TO REGISTER UNDER A REGISTRATION STANDARD

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Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or re-registering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"(A) its composition is such as to warrant the proposed claims for it;
(B) its labeling and other material required to be submitted comply with the requirements of this Act;
(C) it will perform its intended function without unreasonable adverse effects on the environment; and
(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a 'product by product' basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the 'product by product' approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 2, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to re-register all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the 'product by product' approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or re-registration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticides safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

Requirement to Re-register Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to re-register all currently registered products as expeditiously as possible. Congress also agreed that re-registration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for re-regisration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for re-registration set forth in the Guidance Package which accompanies this Standard.

"Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 1978 (43 FR 29686, July 10, 1978, and 43 FR 37336, August 2, 1978), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the second chapter.)

The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

(A) data that is "product specific," i.e., data that relates only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

(B) "generic" data that pertains to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or re-registration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert," ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he re-registers his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, re-registration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which is described by all the following criteria:

(1) the data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;

(2) the data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an

experimental use permit, an amendment adding a new use to a registration, or for re-registration, or to support or maintain in effect an existing registration;

(3) the data are relevant to the Agency's decision to register or re-register the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

(4) the data are determined by EPA to be valid and usable in reaching regulatory conclusions; and

(5) the data are not those for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for re-registration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or re-registration of a manufacturing-use product, and each applicant for registration or re-registration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for re-registration (or new registration) under this Standard is found in the Guidance Package for this Standard.

Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in its summary second chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product specific" data gaps on a 'product by product' basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of re-registering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether that data in question is "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued for publication.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

II. AGENCY POSITION ON CHLORONEB

Regulatory Position for Chloroneb

Chloroneb (1,4-dichloro-2,5-dimethoxybenzene) as described in this Standard may be registered for sale, distribution, reformulation and use in the United States. Considering all available information on products registered on or before May 15, 1980, the Agency finds that none of the risk criteria found in section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations were met or exceeded for chloroneb.

The Agency has determined that chloroneb does not cause an unreasonable adverse effect with proper label directions and precautions. Chloroneb products currently registered may be reregistered subject to the conditions imposed for data requirements. New products may be registered under this Standard and are subject to the same requirements.

Criteria for Registration Under the Standard

To be subject to this Standard, chloroneb products must meet the following conditions:

- contain chloroneb as the sole active ingredient;
- bear required labeling; and
- be within acute toxicity limits.

Manufacturing-use chloroneb products must bear label directions for formulation into acceptable end-uses.

The applicant for registration or reregistration of chloroneb products subject to this Standard must comply with all terms and conditions described in this Standard including commitment to fill data gaps on a time schedule specified by the Agency and when applicable offer to pay compensation to the extent required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act [FIFRA], as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D).

The following registrants have submitted data in support of chloroneb registrations, and have not waived their rights to compensation for this data: E.I. duPont de Nemours and Co., Inc. and O.M. Scott and Sons Co.

A. Manufacturing-use Chloroneb

1. Acceptable Ranges and Limits

a. Product Composition Standard

To be covered under this Standard, manufacturing-use chloroneb products with any percentage of active ingredient are acceptable with appropriate certification of limits.

The Agency identified the possibility of chlorinated dioxin formation, including TCDD, during manufacture of chloroneb. To be covered under this standard, applicants for registration of manufacturing-use chloroneb products must demonstrate that the manufacturing process will not result in the formation of 2,3,7,8-tetrachlorobenzo-p-dioxin (TCDD).

b. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use chloroneb products which have established Toxicity Category I through IV ratings for each of the following acute effects:

Acute Oral Toxicity;
Acute Dermal Toxicity
Acute Inhalation Toxicity;
Primary Eye Irritation; and
Primary Dermal Irritation.

c. Use Patterns

To be covered under this Standard, manufacturing-use chloroneb must be formulated into end-use fungicides which are intended for outdoor nondomestic terrestrial uses (food or nonfood).

2. Data Requirements and Data Gaps

Applicants for registration of manufacturing-use chloroneb products with all acceptable end-uses must cite or submit the following information on the physical/chemical properties, composition, fate and toxicity of the proposed product. Data in this Standard that satisfy registration requirements may be cited, if the applicant establishes that the proposed product is substantially similar to another product for which the Agency has received acceptable acute toxicity tests. Data may be cited provided compensation has been offered to the submitters of these studies. The Agency will consider both active and inert ingredients in the determination of substantially similar products. Before each requirement is listed the section of the Proposed Guidelines which describes that type of data and when it is required [43 FR, No. 132, 29696 of July 10, 1978; and 43 FR, No. 163, 37336 of August 22, 1978]. Applicants for the reregistration of manufacturing-use chloroneb must sumbit all information identified as data gaps (see charts).

PRODUCT CHEMISTRY

			Data Gaps		
Data Requirements	Food Use	Nonfood Use	Food Use	Nonfood Use	Test Substance
163.61-3 Product Identity	X	X			
163.61-4 Composition Starting Materials	X	X			
163.61-4 Manuf. Process	X	X	X	X	Technical Grade
163.61-3 Disc. of Ingred.	X	X			
163.61-5 Disc. of Unint. Ingredients	X	X	X	X	Technical Grade
163.61-6 Certification of Limits	X	X	X	X	Manufacturing-use Product
163.61-7 Analyt. Meth./Data	X	X	X(data)	X(data)	Technical Grade and/or Manufacturing-use Produc
163.61-8 Color	X	X			
163.61-8 Odor	X	X			
163.61-8 Melting Point	X	X			
163.61-8 Solubility	X	X			
163.61-8 Stability	X	X			
163.61-8 Oct./Water Part. Coefficient	X	X	X	X	Technical Grade
163.61-8 Physical State	X	X			
163.61-8 Density or Specific Gravity	X	X			
163.61-8 Vapor Pressure	X	X			
163.61-8 pH	X	X	X	X	Technical Grade and/or Manufacturing-use Produc
163.61-8 Storage Stability	X	X	X	X	Manufacturing-use Product
163.61-8 Flammability	X	X	X	X	Manufacturing-use Product
163.61-8 Oxidizing/Reducing Action	X	X	X	X	Manufacturing-use Product
163.61-8 Explosiveness	X	X	X	X	Manufacturing-use Product
163.61-8 Corrosion Characteristics	X	X	X	X	Manufacturing-use Product

TOXICOLOGY

			Data Gaps		
Data Requirements	Food Use	Nonfood Use	Food Use	Nonfood Use	Data Which Must be Cited
163.81-1 Acute Oral Tox.	X	X			GS0007-010
163.81-2 Acute Dermal Tox.	X	X	X	X	
163.81-3 Acute Inhal. Tox.	X	X	X	X	
163.81-4 Primary Eye Irritation*	X	X			GS0007-011
163.81-5 Primary Dermal Irritation	X	X			GS0007-012
163.81-6 Skin Sensitization	X	X	X	X	
163.82-1 Subchronic Oral Tox.	X	X			
163.82-2 Subchronic (21 day) Dermal Tox.	X	X			
163.83-1 Chronic Feeding	X		X		
163.83-2 Oncogenicity	X		X		
163.83-3 Teratogenicity	X	X	X	X	
163.83-4 Reproduction	X		X		
163.83-1 Mutagencity through -4	X	X	X	X	
163.85-1 Metabolism	X		X		

*Primary Eye Irritation test or demonstration of pH between 1 and 3 or 12 and 14 or demonstration of dermal irritation of Category I.

ENVIRONMENTAL FATE

Data Requirements	Food Use	Nonfood Use	Data Gaps		Data Which Must be Cited
			Food Use	Nonfood Use	
163.62-7 Hydrolysis	X	X			
163.62-7 Photolysis	X	X	X	X	
163.62-8 Aerobic/Anerobic Soil Metab.	X	X(aerobic)	X	X(aerobic)	
163.62-8 Microbes on Chloroneb	X	X	X	X	00001426
163.62-8 Chloroneb on Microbes	X	X	X	X	
163.62-8 Activated Sludge Metabolism	X	X			GS0007-007
163.62-9 Leaching	X	X	X	X	
163.62-9 Adsorption/Desorption	X	X	X	X	
163.62-10 Terrestrial Field Dissip.	X	X	X	X	
163.62-11 Rotational Crop	X		X		
163.62-11 Fish Accumulation	X	X	X	X	

RESIDUE CHEMISTRY

Data Requirements (Food Use)	Data Gaps	Data Which Must be Cited
Metabolism in Plants		
Metabolism in Animals	X	
Analytical Methods		
Residue Data: Crops		
Snap Beans/Dried Beans	X(Beans/Bean Vines)	
Soybeans	X(and Soybean Vines)	
Sugarbeets	X	
Cottonseed/Cotton Forge	X	
Residue Data: Processed Crops		
Cottonseed	X	
Soybeans	X	
Sugarbeets	X	
Residue Data:		
Milk and Meat	X	
Storage and Stability	X	

Residue Chemistry Data Gaps

1) Data on the metabolism of chloroneb in food animals. Available data are qualitative, whereas quantitative as well as qualitative data on the disposition of chloroneb in food animals are required.

2) Data on residues in beans and bean vines (forage), soybeans and soybean vines (forage), cottonseed and cotton forage, and sugarbeets (roots and tops). Available data were not submitted in raw* form and, with the exception of the data on beans, were obtained on an inadequate number of samples.

3) Information on the storage of agricultural commodities between sampling and residue analysis. Data on storage conditions and on the stability of residues during sample storage are required. No data are available.

4) Data on residues in fractions of processed cottonseed, soybeans, and sugarbeets. No data are available. The data would not be required if residues in raw agricultural commodities are low enough that residues in processed commodities would not likely exceed 0.1 ppm, the tolerance on the raw commodities. The Agency assumes a maximum concentration factor of 5 in processing cottonseed and soybeans to oil, and a factor of 20 in processing sugarbeets to dried pulp. Therefore, fractionation studies would not be required if residues on cottonseed and soybeans were less than .02 ppm (.1ppm/5), and residues on sugarbeets were less than .005 ppm (.1ppm/20).

5) Data on whether residues are transferred from items of animal feed to meat and milk. Available data were obtained on too few animals, and were not submitted in raw* form.

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*Raw data are data which are uncorrected for reagent blanks, untreated crop blanks, and recovery of fortified samples.

ECOLOGICAL EFFECTS

Data Requirements	Food Use	Nonfood Use	Data Gaps Food Use	Data Gaps Nonfood Use	Data Which Must be Cited
163.72-1 Freshwater Fish LC50	X	X			
Coldwater	X	X			GS0007-003
Warmwater	X	X	X	X	GS0007-004
163.71-1 Bird Single Dose	X	X	X	X	
Oral LD50					
163.71-2 Bird Subacute	X	X			GS0007-002
Dietary LC50					GS0007-001
163.72-2 Aquatic Invertebrates	X	X			GS0007-005

3. Required Labeling

All manufacturing-use chloroneb products must bear appropriate labeling as specified in 40 CFR 162.10.

a. Use Pattern Statements

All manufacturing-use chloroneb products must list on the label the intended end-uses of formulated products produced from the manufacturing-use products. In accordance with data to be submitted or cited, all chloroneb product labels must bear one of the following statements:

> "For Formulation into End-Use Fungicide Products Intended _Only_ for Nondomestic, Food, Outdoor Use"; or

> "For Formulation into End-Use Fungicide Products Intended _Only_ for Nondomestic, Nonfood, Outdoors Use"; or

> "For Formulation into End-Use Fungicide Products Intended _Only_ for Nondomestic, Food or Nonfood, Outdoors Use".

Presented below are the types of statements which must appear on manufacturing-use chloroneb labels. See 40 CFR 162.10 for specific required labeling for manufacturing-use products.

PRODUCT NAME

"For Formulation into End-Use Fungicide Products Intended Only for Nondomestic, Food, Outdoor Use."

ACTIVE INGREDIENT:

Chloroneb (1,4-dichloro-2,5-dimethoxybenzene)............ %(min)

INERT INGREDIENTS:.................. _____%

100%

CAUTION

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

May irritate eyes, nose, throat, and skin. Avoid breathing dust. Avoid contact with skin, eyes and clothing.

First Aid Statement: In case of contact, immediately flush skin or eyes with plenty of water. Get medical attention if irritation persists.

Environmental Hazards

Do not discharge into lakes, streams, ponds, or public waters unless in accordance with an NPDES permit. For guidance, contact your regional office of EPA.

Directions for Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Refer to technical bulletin.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal. Do not re-use empty container; bury in a safe place away from water supplies. Consult federal, state, or local disposal authories for approved alternative procedures such as limited open burning. Open dumping is prohibited.

EPA Registration No. ____________
Establishment No. ____________
Net Wt. or Measure ____________

Name and Address of the producer, registrant, or person for whom produced.

4. Tolerance Reassessment

Tolerances have been established for residues of chloroneb and its metabolite, 2,5-dichloro-4-methoxyphenol (calculated as chloroneb), in or on raw agricultural commodities as indicated: 2 ppm in or on cotton forage, bean vines, and soybean vines; 0.2 ppm in or on meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep; 0.1 ppm (neglible residue) in or on beans, cottonseed, soybeans, and sugarbeets (roots and tops); and 0.05 ppm (negible residue) in milk (40 CFR 180.257).

The theoretical maximum residue contribution (TMRC) of chloroneb to the human diet is calculated to be .064 mg/day. This figure is based on average adult eating patterns and on the assumption that each commodity contains residues which meet the established tolerance level.

The Agency has calculated a tentative acceptable daily intake (ADI) value of .125 milligrams of chloroneb per kilogram of body weight per day. This value is based on a "no-observed-effect" level (NOEL) of 500 ppm established in a two year dog study, and the incorporation of a 100 fold safety factor in translating the data from animal to man. This ADI value can only be considered tentative until the Agency is able to verify the NOEL through the submission of additional required chronic effects data (see Toxicology data gaps).

From available data, the Agency has established a maximum permissible intake (MPI) value of 7.5 mg/day for an average (60 kg.) adult (ADI X 60 kg = MPI).

The theoretical maximum residue contribution of chloroneb to the diet is less than the maximum permissible intake (.064 mg/day is less than 7.5 mg/day). Current tolerance levels appear to be more than adequate.

5. Regulatory Rationale

a. Data Gaps

Data on physical and chemical properties and acute toxicity are required for all chloroneb manufacturing-use products. Chloroneb's food use and the need for tolerances for those uses is the basis for chloroneb's chronic toxicology data requirements. The nonfood-nondomestic use pattern of chloroneb requires subchronic testing and teratogenicity, and mutagenicity data. Chronic studies for the nonfood, nondomestic use pattern are not currently required because the use pattern is not expected to result in repeated exposure over a significant portion of the human life span.

B. Wettable Powder Chloroneb

1. Acceptable Ranges and Limits

a. Product Composition Standard

To be covered under this Standard, wettable powder chloroneb products with any percentage of ingredients are acceptable with appropriate certification of limits.

Inert ingredients in food-use formulations must be cleared for such use under 40 CFR 180.1001.

b. Acute Toxicity Limits

To be registered for nondomestic use under this Standard, wettable powder chloroneb products must have Toxicity Category II through IV ratings for each of the following acute effects:

Acute Oral Toxicity;
Acute Dermal Toxicity
Acute Inhalation Toxicity;
Primary Eye Irritation; and
Primary Dermal Irritation.

c. Use Patterns and Application Methods

To be registered under this Standard, WP products of chloroneb may be used only as a fungicide on cotton, beans, soybeans, and sugarbeets or ornamental turf.

The Agency considers chloroneb use as a seed treatment on cotton, beans, soybeans, and sugarbeets, and in-furrow soil treatment for cotton, beans, and soybeans to be a food use. The use on ornamental turfgrass does not constitute a food use with the restriction that grazing or feeding of clippings from treated areas to livestock is prohibited.

The Agency finds that current dosage rates and application methods are acceptable under this Standard.

2. Data Requirements and Data Gaps

Applicants for registration of wettable powder chloroneb products must cite or submit the following information on the physical/chemical properties, composition, and acute toxicity of the proposed product. If the applicant establishes that a product is substantially similar to another product, for which the Agency has received acceptable acute toxicity tests, these data may be cited provided compensation has been offered to the submitters of these studies. The Agency will consider both active and inert ingredients in making the determination of substantially similar products.

The Agency has not received acceptable acute toxicity data or product chemistry data for any wettable powder chloroneb product. The Agency has determined that no existing wettable powder chloroneb product is substantially similar to another. Therefore, all required acute toxicity tests and product chemistry data are needed for each currently registered wettable powder product.

Applicants are hereby advised that if the Agency does not receive commitments, within the specified time frame, from maufacturing-use chloroneb producers to fill data gaps identified for the manufacturing-use product, manufacturing-use product registrations will be suspended. Formulators must then bear the burden of supplying the data if formulators want the manufacturing-use product to be available.

WETTABLE POWDER

Data Requirements	Food Use	Nonfood Use	Data Gaps Food Use	Data Gaps Nonfood Use	Data Which Must be Cited
Product Chemistry					
163.61-7 Analytical Methods and Data	X	X	X	X	
163.61-6 Certification of Limits	X	X	X	X	
163.61-8 Color	X	X	X	X	
163.61-8 Odor	X	X	X	X	
163.61-8 Density or Specific Gravity	X	X	X	X	
163.61-8 pH	X	X	X	X	
163.61-8 Storage Stability	X	X	X	X	
163.61-8 Flammability	X	X	X	X	
163.61-8 Oxidizing/Reducing Action	X	X	X	X	
163.61-8 Explosiveness	X	X	X	X	
163.61-8 Corrosion Characteristics	X	X	X	X	
Toxicology					
163.81-1 Acute Oral Toxicity	X	X	X	X	
163.81-2 Acute Dermal Toxicity	X	X	X	X	
163.81-3 Acute Inhalation Toxicity	X	X	X	X	
163.81-4 Primary Eye Irritation[1]	X	X	X	X	
163.81-5 Primary Dermal Irritation	X	X	X	X	
163.81-6 Skin Sensitization	X	X	X	X	

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[1] A demonstration of pH between 1 and 3 or 12 and 14 or a demonstration of dermal corrosiveness will allow the Agency to establish that a product is corrosive to the eye, an an eye irritation test need not be performed.

3. Required Labeling

All wettable powder chloroneb products must bear appropriate labeling as specified in 40 CFR 162.10.

All labels and labeling intended for agricultural use products must bear the following statement: "This product must be applied in accordance with 40 CFR Part 170." Registrants may state the contents of 40 CFR Part 170 or additional statements.

Presented below are types of statements which must appear on wettable powder chloroneb labels. See 40 CFR 162.10 for specific required labeling for formulated products.

PRODUCT NAME

ACTIVE INGREDIENT:

Chloroneb (1,4-dichloro-2,5-dimethoxybenzene)............ %(min)

INERT INGREDIENTS:.................. %

100%

Keep out of reach of children.

CAUTION

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

May irritate eyes, nose, throat, and skin. Avoid breathing dust. Avoid contact with skin, eyes and clothing.

Other Prohibitions

Seed Treatment

Do not use treated seed for food, feed, or oil purposes.

For use on beans and soybeans: Do not graze on treated plants within 45 days of planting.

Ornamental Turf

Do not allow grazing or feeding of clippings from treated areas to livestock.

Directions for Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Registered Appplication Rates

Formulation	Site	Type of Applic.	Application rate (lb. or oz. a.i.)
Wettable Powder (65%)	cotton	seed	3.9 oz/100 lb seed 6.5 oz/100 lb seed
		furrow	1.3-1.9 lb/A
	sugarbeets	seed	3.9 oz/100 lb seed
	beans	seed	2.6 oz/100 lb seed
		furrow	.98 lb/A
	soybeans	seed	2.6 oz/100 lb seed
		furrow	.98 lb/A
	turf	foliar	7.08 lb/A for *Pythium* blight 10.6-15.9 lb/A for snow mold

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal. Do not re-use empty container; bury in a safe place away from water supplies. Consult federal, state, or local disposal authories for approved alternative procedures such as limited open burning. Open dumping is prohibited.

Name and Address of the producer, registrant, or person for whom produced.

EPA Registration No. ____________
Establishment No. ____________
Net Wt. or Measure ____________

4. Regulatory Rationale

Wettable powder chloroneb may be registered for use in the United States. The registration is dependent upon filling the data gaps identified in the disciplinary chapters of wettable powder chloroneb and upon meeting standards for nondomestic use.

a. Acceptable Ranges and Limits

Product Composition Standards

The Agency will consider for registration wettable powder chloroneb products which contain chloroneb as the sole active ingredient if the products meet the acute toxicity standards for nondomestic use, and if the inert ingredients in food-use formulations have been cleared under 40 CFR 180.1001.

Acute Toxicity Limits

The Agency will register wettable powder chloroneb products for nondomestic use that have acute toxicity category II through IV ratings because the nondomestic user can be expected to take precautions associated with Category II pesticides.

Use Patterns and Application Methods

Wettable powder chloroneb products may be registered for nondomestic use as a fungicide seed or infurrow soil treatment only for cotton, soybeans, and beans, and as a seed treatment only on sugarbeets. It may also be registered for nondomestic use on ornamental turf.

The Agency finds that currently registered dosage rates and application methods are acceptable pending submission of required residue chemistry data listed in the manufacturing-use standard. There is no data to suggest that maximum dosage rates on currently registered labels would produce residues that would exceed tolerances set for chloroneb.

C. Granular Chloroneb

1. Acceptable Ranges and Limits

a. Product Composition Standards

To be covered under this Standard, granular chloroneb products with any percentage of ingredients are acceptable with appropriate certification of limits.

Inert ingredients in food-use formulations must be cleared for such use under 40 CFR 180.1001.

b. Acute Toxicity Limits

To be registered for non-domestic use under this Standard, granular chloroneb products must have Toxicity Category II through IV ratings for each of the following acute effects:

Acute Oral Toxicity;
Acute Dermal Toxicity
Acute Inhalation Toxicity;
Primary Eye Irritation; and
Primary Dermal Irritation.

c. Use Patterns and Application Methods

To be registered under this Standard, granular products of chloroneb may be used only as a fungicide on cotton, beans, soybeans or ornamental turf.

The Agency considers chloroneb use as an in-furrow soil treatment for cotton, beans, and soybeans to be a food use. The use on ornamental turfgrass does not constitute a food use with the restriction that grazing or feeding of clippings from treated areas to livestock is prohibited.

The Agency finds that current dosage rates and application methods are acceptable under this Standard.

2. Data Requirements and Data Gaps

Applicants for registration of granular chloroneb products must cite or submit the following information on the physical/chemical properties, composition and acute toxicity of the proposed product. Data in this Standard that satisfy registration requirements may be cited, if the applicant establishes that the proposed product is substantially similar to another product for which the Agency has acceptable acute toxicity tests. Data may be cited provided compensation has been offered to the submitters of these studies. The Agency will consider both active and inert ingredients in making determinations of substantial similarity.

The Agency has received acceptable acute toxicity data for some categories of tests for one granular product (see Topical Discussions). No product chemistry data were available. The Agency has determined that no existing granular chloroneb product is substantially similar to another. Therefore, all acute toxicity tests and product chemistry data are required of each product. The guidance package accompanying this standard identifies the single product for which the Agency has received acceptable acute toxicity data.

Applicants are hereby advised that if the Agency does not receive commitments, within the specified time frame, from manufacturing-use chloroneb producers to fill data gaps identified for the manufacturing-use material, the registrations of manufacturing-use products will be suspended. Formulators must then bear the burden of supplying this data if continued availability of the manufacturing-use product is desired.

GRANULAR

Data Requirements	Food Use	Nonfood Use	Data Gaps Food Use	Data Gaps Nonfood Use	Data Which Must be Cited
Product Chemistry					
163.61-7 Analytical Methods and Data	X	X	X	X	
163.61-6 Certification of Limits	X	X	X	X	
163.61-8 Color	X	X	X	X	
163.61-8 Odor	X	X	X	X	
163.61-8 Density or Specific Gravity	X	X	X	X	
163.61-8 pH	X	X	X	X	
163.61-8 Storage Stability	X	X	X	X	
163.61-8 Flammability	X	X	X	X	
163.61-8 Oxidizing/Reducing Action	X	X	X	X	
163.61-8 Explosiveness	X	X	X	X	
163.61-8 Corrosion Characteristics	X	X	X	X	
Toxicology					
163.81-1 Acute Oral Toxicity[1]	X	X	X	X	
163.81-2 Acute Dermal Toxicity	X	X	X	X	
163.81-3 Acute Inhalation Toxicity	X	X	X	X	
163.81-4 Primary Eye Irritation[1]	X	X	X	X	
163.81-5 Primary Dermal Irritation[1]	X	X	X	X	
163.81-6 Skin Sensitization	X	X	X	X	

[1] The Agency has received acceptable acute oral LD50 data and primary dermal irritation data for one registered granular product. See guidance package accompanying this Standard for information on the identity of this product.

[2] A demonstration of pH between 1 and 3 or 12 and 14 or a demonstration of dermal corrosiveness will allow the Agency to establish that a product is corrosive to the eye, and an eye irritation test need not be performed.

3. Required Labeling

All granular chloroneb products must bear appropriate labeling as specified in 40 CFR 162.10. All labels and labeling intended for agricultural use products must bear the following statement: "This product must be applied in accordance with 40 CFR Part 170." Registrants my state the contents of 40 CFR Part 170 or additional statements.

Presented below are types of statements which must appear on granular chloroneb labels. See 40 CFR 162.10 for specific required labeling for formulated products.

PRODUCT NAME

ACTIVE INGREDIENT:

Chloroneb (1,4-dichloro-2,5-dimethoxybenzene)............ %(min)

INERT INGREDIENTS:.................. _____%

100%

Keep out of reach of children.

CAUTION

PRECAUTIONARY STATEMENT

Hazards to Humans and Domestic Animals

May irritate eyes, nose, throat, and skin. Avoid breathing dust. Avoid contact with skin, eyes and clothing.

Other Prohibitions

Seed Treatment

Do not use treated seed for food, feed, or oil purposes.

For use on beans and soybeans: Do not graze on treated plants within 45 days of planting.

Ornamental Turf

Do not allow grazing or feeding of clippings from treated areas to livestock.

Directions for Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Registered Appplication Rates

Formulation	Site	Type of Applic.	Application rate (lb. or oz. a.i.)
Granular (1.015-10%)	turf	foliar	7.1-16.6 lb/A
	cotton	furrow	1-2 lb/A
	beans	furrow	1 lb/A
	soybeans	furrow	1 lb/A

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal. Do not re-use empty container; bury in a safe place away from water supplies. Consult federal, state, or local disposal authorities for approved alternative procedures such as limited open burning. Open dumping is prohibited.

Name and Address of the producer, registrant, or person for whom produced.

EPA Registration No. ______________
Establishment No. ________________
Net Wt. or Measure ________________

4. Regulatory Rationale

Granular chloroneb may be registered for nondomestic use in the United States. The registration is dependent upon filling the data gaps identified in the disciplinary chapters of granular chloroneb and upon meeting standards for nondomestic use.

a. Acceptable Ranges and Limits

Product Composition Standards

The Agency will consider for registration granular chloroneb products which contain chloroneb as an active ingredient if the products meet the acute toxicity standards for non-domestic general use, and if inert ingredients in food-use formulations have been cleared under 40 CFR 180.1001.

Acute Toxicity Limits

The Agency will register granular chloroneb products for nondomestic use that have acute toxicity category II through IV ratings because the nondomestic user can be expected to take precautions associated with Category II pesticides.

Use Patterns and Application Methods

Granular chloroneb products may be registered for nondomestic use as a fungicide infurrow soil treatment only for cotton, soybeans, and beans. It may also be registered for nondomestic use on ornamental turf.

The Agency finds current dosage rates and application methods acceptable. There are no data to suggest that maximum dosage rates on currently registered labels would produce residues that would exceed tolerances set for chloroneb.

D. Dust Chloroneb

1. Acceptable Ranges and Limits

a. Product Composition Standards

To be covered under this Standard, dust chloroneb products with any percentage of ingredients are acceptable with appropriate certification of limits.

Inert ingredients in food-use formulations must be cleared for such use under 40 CFR 180.1001.

b. Acute Toxicity Limits

To be registered for nondomestic use under this Standard, dust chloroneb products must have Toxicity Category II through IV ratings for each of the following acute effects:

1) Acute Oral Toxicity;
2) Acute Dermal Toxicity;
3) Acute Inhalation Toxicity;
4) Primary Eye Irritation; and
5) Primary Dermal Irritation.

c. Use Patterns and Application Methods

To be under this Standard, dust products of chloroneb may be used only as a fungicide on cotton, beans or soybeans.

The Agency considers chloroneb use as a seed treatment or in-furrow soil treatment to be a food use.

The Agency finds that dosage rates and application methods on currently registered labels are acceptable under this Standard.

2. Data Requirements and Data Gaps

Applicants for registration of dust chloroneb products must cite or submit the following information on the physical/chemical properties, composition, and acute toxicity of the proposed product. If the applicant establishes that a product is substantially similar to another product for which the Agency has received acceptable acute toxicity tests, this data may be cited provided compensation has been offered to the submitters of these studies. Both active and inert ingredients will be considered in making determination of substantial similarity.

The Agency has not received acceptable acute toxicity or product chemistry data for any category of test, for any dust chloroneb product. The Agency has determined that no existing dust chloroneb product is substantially similar to another. Therefore, all acute toxicity tests and product chemistry data are required of each dust chloroneb product.

Applicants are hereby advised that if the Agency does not receive commitments, within the specified time frame, from manufacturing-use chloroneb producers to fill gaps identified for the manufacturing-use material, the registrations of manufacturing-use products will be suspended. Formulators must then bear the burden of supplying this data if continued availability of the manufacturing-use product is desired.

DUST

Data Requirements	Food Use	Nonfood Use	Data Gaps Food Use	Data Gaps Nonfood Use	Data Which Must be Cited
Product Chemistry					
163.61-7 Analytical Methods and Data	X	X	X	X	
163.61-6 Certification of Limits	X	X	X	X	
163.61-8 Color	X	X	X	X	
163.61-8 Odor	X	X	X	X	
163.61-8 Density or Specific Gravity	X	X	X	X	
163.61-8 pH	X	X	X	X	
163.61-8 Storage Stability	X	X	X	X	
163.61-8 Flammability	X	X	X	X	
163.61-8 Oxidizing/Reducing Action	X	X	X	X	
163.61-8 Explosiveness	X	X	X	X	
163.61-8 Corrosion Characteristics	X	X	X	X	
Toxicology					
163.81-1 Acute Oral Toxicity	X	X	X	X	
163.81-2 Acute Dermal Toxicity	X	X	X	X	
163.81-3 Acute Inhalation Toxicity	X	X	X	X	
163.81-4 Primary Eye Irritation[1]	X	X	X	X	
163.81-5 Primary Dermal Irritation	X	X	X	X	
163.81-6 Skin Sensitization	X	X	X	X	

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[1] A demonstration of pH between 1 and 3 or 12 and 14 _or_ a demonstration of dermal corrosiveness will allow the Agency to establish that a product is corrosive to the eye, and an eye irritation test need not be performed.

3. Required Labeling

All dust chloroneb products must bear appropriate labeling as specified in 40 CFR 162.10. All labels and labeling intended for agricultural use products must bear the following statement: "This proudct must be applied in accordance with 40 CFR Part 170." Registrants may state the contents of the 40 CFR Part 170 or additional statements.

Presented below are types of statements which must appear on dust chloroneb labels. Refer to 40 CFR 162.10 for specific labeling requirements for formulated products.

PRODUCT NAME

ACTIVE INGREDIENT:

Chloroneb (1,4-dichloro-2,5-dimethoxybenzene)............ %(min)

INERT INGREDIENTS:.................. %

100%

Keep out of reach of children.

CAUTION

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

May irritate eyes, nose, throat, and skin. Avoid breathing dust. Avoid contact with skin, eyes and clothing.

Other Prohibitions

Seed Treatment
Do not use treated seed for food, feed, or oil purposes.

For use on beans and soybeans: Do not graze on treated plants within 45 days of planting.

Direction for Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Registered Appplication Rates

Formulation	Site	Type of Applic.	Application rate (lb. or oz. a.i.)
Dust (10%)	cotton	seed	.5 lb/100 lb seed
		furrow	1-2 lb/A
	beans	seed	.2 lb/100 lb seed
		furrow	1 lb/A
	soybeans	seed	.2 lb/100 lb seed
		furrow	1 lb/A

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal. Do not re-use empty container; bury in a safe place away from water supplies. Consult federal, state, or local disposal authories for approved alternative procedures such as limited open burning. Open dumping is prohibited.

Name and Address of the producer, registrant, or person for whom produced.

EPA Registration No. ______________
Establishment No. ________________
Net Wt. or Measure ________________

4. Regulatory Rationale

Dust chloroneb may be registered for nondomestic use in the United States. The registration is dependent upon filling the data gaps identified in the disciplinary chapters of dust chloroneb and upon meeting description of nondomestic use.

a. Acceptable Ranges and Limits

Product Composition Standards

The Agency will consider for registration dust chloroneb products which contain chloroneb as the sole active ingredient if the products meet the acute toxicity standards for nondomestic use, and if the inert ingredients in food-use formulations have been cleared under 40 CFR 180.1001.

Acute Toxicity Limits

The Agency will register dust chloroneb products for nondomestic use that have acute toxicity category II through IV ratings because the nondomestic user can be expected to take precautions associated with Category II pesticides.

Use Patterns and Application Methods

Dust chloroneb products may be registered for nondomestic use as a fungicide seed or infurrow soil treatment only for cotton, soybeans, and beans.

The Agency finds that currently registered dosage rates and application methods are acceptable pending submission of required residue chemistry data listed in the manufacturing-use standard. There is no data to suggest that maximum dosage rates on currently registered labels would produce residues that would exceed tolerances set for chloroneb.

III. PRODUCT CHEMISTRY

Introduction

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. The Agency requires registrants to provide quantitative data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Further, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower composition limits for the added ingredients, or upper limits only for some unintentional ingredients. Subpart D of the Proposed Guidelines (43 FR 29696, July 10, 1978) suggests specific precision limits for ingredients based on the percentage of ingredient and the standard deviation of the analytical method.

In addition to the data on product composition, the Agency guidelines also require data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. For example, data are needed concerning the identity and physical state of the active ingredient (e.g., melting and boiling point data, ambient vapor pressure and solubility). Data are also required on the properties of the formulated product to establish labeling cautions (e.g., flammability, corrosiveness or storage stability). The Agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

Product Chemistry - Manufacturing-Use Chloroneb

Product Chemistry Profile

One manufacturing use product containing approximately 90% chloroneb is currently registered.

A detailed manufacturing procedure was not available to the Agency. The two major routes by which technical chloroneb could be synthesized involve either direct chlorination of 1,4-dimethoxy-benzene, or chlorination of quinone or hydroquinone followed by methylation. With either of these routes there exists the possibility of chlorinated dioxin formation including TCDD depending on the reaction conditions and on the purity of starting materials.

Methods for the determination of chloroneb in wettable powder formulations, the determination of chloroneb in the technical chemical, and the determination of volatile impurities in the technical chemical have been submitted to the Agency.

A small amount of data are available on the physical and chemical properties of technical chloroneb.

Data Requirements

Listed below are Product Chemistry data needed to adequately support the registration of any manufacturing-use chloroneb product. Following each data requirement is the section in the Proposed Guidelines for the Registration of Pesticides in the United States (43 FR 29696, July 10, 1978) that describes the type of data required. The applicant for registration must submit or cite the following information.

For Manufacturing-Use Chloroneb:

1) Product Identity ....163.61-3(a)
2) Identification of all impurities exceeding 0.1% of the weight of the technical chloroneb product...............163.61-3(c)
3) Composition of the starting materials used to manufacture technical chloroneb...163.61-4(a)
4) Detailed manufacturing process for technical chloroneb......................163.61-4(b)
5) Discussion on the formation of unintentional ingredients during the manufacture of technical chloroneb........163.61-5
6) Declaration of Limits....................163.61-6(a)
7) Certification that limits on the active ingredient and impurities in technical chloroneb will be maintained for all quantities of the product sold or distributed in interstate commerce........163.61-6(b)
8) Analytical method and data on the composition of technical chloroneb. Data on the active ingredient and each identifiable impurity exceeding 0.1% of the product weight are to be obtained on five or more samples of the product...............163.61-7(b)

9) Physical and chemical properties.

a) Color	163.61-8(c)(1)
b) Odor	163.61- (c)(2)
c) Melting point	163.61-8(c)(3)
d) Solubility (in quantitative terms)	163.61-8(c)(4)
e) Stability	163.61-8(c)(5)
f) Octanol/water partition coefficient	163.61-8(c)(6)
g) Physical state	163.61-8(c)(7)
h) Density or Specific Gravity.	163.61-8(c)(8)
i) Boiling Point	163.61-8(c)(9)
j) Vapor Pressure	163.61-8(c)(10)
k) pH	163.61-8(c)(11)
i) Storage Stability	163.61-8(c)(12)
m) Flammability	163.61-8(c)(13)
n) Oxidizing and Reducing Action	163.61-8(c)(14)
o) Explosiveness	163.61-8(c)(15)
p) Corrosion Characteristics	163.61-8(c)(18)

Data Gaps

Manufacturing Process	163.61-4
Formation of Unintentional Ingredients	163.61-5
Active Ingredient Limits	163.61-6
Data Obtained from Analytical Methods	163.61-7
Physical/Chemical Properties	163.61-8
Octanol/Water Partition Coefficient	
pH	
Storage Stability	
Flammability	
Oxidizing/Reducing Action	
Explosiveness	
Corrosion Characteristics	

Topical Discussions

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines for Registering Pesticides' in the United States (43 FR 29696, July 10, 1978) which explains the minimum data that the Agency requires in order to adequately assess Product Chemistry of manufacturing-use chloroneb products. Also, under each of the following topics is a reference to the appropriate section in the 'Proposed Guidelines'.

	Guidelines Section
Chemical Identity	163.61-3
Manufacturing Processes	163.61-4
Formation of Unintentional Ingredients	163.61-5

Active Ingredient Limits in Pesticide Products....................163.61-6
Product Analytical Methods and Data............163.61-7
Physical/Chemical Properties..................163.61-8

Chemical Identity

The Proposed Guidelines require identifying information including chemical names, product names, and numerical codes of all substances known or assumed to be present in pesticide products. [163.61-3(c)]

"Chloroneb" is the common name accepted by the American National Standards Institute (ANSI) for the chemical 1,4-dichloro-2,5-dimethoxybenzene. (Fig. 1). Chloroneb is also known by the trade names "Demosan", Soil Fungicide 1823, and "Tersan". The Chemical Abstracts Registry (CAS) number for chloroneb is 2675-77-6, and the EPA Shaughnessy number is 027301. The common name will be used throughout this standard in lieu of other chemical or trade names.

Manufacturing Processes

Because the route by which a pesticide is synthesized determines the nature and amount of potentially toxic impurities, a detailed description of the manufacturing process is required. [163.61-4]

Technical chloroneb could be synthesized by two major routes which involve either direct chlorination of 1,4-dimethoxybenzene or chlorination of quinone or hydroquinone followed by methylation. Two patent applications (Alvarez 1968, GS 0007-015; Haglid 1979, 05013181) describe several chloroneb manufacturing processes in sufficient detail to satisfy Proposed Guidelines requirements. However, the Agency has no information to indicate which if any of the processes are used presently to manufacture technical chloroneb. A description of the manufacturing process has been submitted to the Agency. This description is not sufficiently detailed to satisfy Guidelines requirements. Company submitted data on manufacture of technical chloroneb is contained in the Confidential Discussion Appendix.

Formation of Unintentional Ingredients

Section 163.61-5 of the Proposed Guidelines requires registrants of manufacturing-use and of formulated products to submit a theoretical discussion of the formation of unintended substances in the product. Of particular relevance to chloroneb would be a discussion of dioxin formation incident to the manufacture of technical chloroneb.

Manufacturing processes for chloroneb found in the patent literature could result in dioxin formation. In one patent application (Scribner and Soboczenski 1966, GS0007-009), six routes by which chloroneb could be synthesized were outlined. In four of these routes, the initial step is chlorination of quinone or hydroquinone. A polychlorinated phenol with a -Cl ortho to an -OH is an intermediate in these syntheses, and thus, depending on reaction conditions, a variety of dioxins may be formed. One of these routes involves basic hydrolysis of 1,2,4,5-tetrachloro-benzene and could thus result in formation of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD).

The remaining routes discussed in Scribner and Soboczenski (1966, GS0007-009) and the synthetic routes discussed in other patent applications (Alvarez 1968, GS0007-015; Haglid 1979, 05013181), involve direct chlorination of 1,4 dimethoxy-benzene and would be less likely to result in dioxin by-products unless there were significant amounts of phenols in manufacturing grade 1,4-dimethoxybenzene.

A theoretical discussion of the formation of unintended substances is required and has not been submitted for technical chloroneb. Such a discussion is required for each technical.

Active Ingredient Limits in Pesticide Products

The Guidelines require that upper and lower limits be established for each active ingredient and each intentionally added inert in a pesticide product [163.61-6]. Technical chloroneb contains approximately 90% of the pure chemical.

Upper and lower limits have not been established and certified for technical chloroneb.

Product Analytical Methods and Data

The Guidelines require submission of, or reference to, analytical methods for measuring each active ingredient in a pesticide product. [163.61-7]

Section 163.61-7 of the Proposed Guidelines also require that applications for registration of pesticide products contain analytical data obtained by methods supplied to the Agency.

Acceptable methods for the determination of chloroneb and impurities in technical chloroneb are contained in the Confidential Discussion Appendix. Data obtained by the method are not available.

Physical and Chemical Properties

For every pesticide product, the Proposed Guidelines require data on certain physical and chemical properties useful for identification purposes or for evaluation of hazard potential [163.61-8].

A small amount of data are available on the physical and chemical properties of chloroneb. Available data on purified chloroneb (du Pont 1977, 00001444) are as follows:

Color: White

Odor: Musty (technical chemical).

Melting point: 133-135°C

Boiling point: 268°C

Density or Specific Gravity: 1.66

Physical State: Purified chloroneb is a crystalline solid.

Solubility: The solubilities of purified chloroneb in selected solvents are as follows: 8 ppm in water at 25°C, 13.3% in methylene chloride, 11.8% in dimethyl formamide, 11.5% in acetone, 8.9% in xylene.

Stability: Chloroneb is temperature stable at least up to the boiling point; stable in water and common organic solvents; stable in the presence of dilute acid or alkali; and subject to microbial decomposition under moist conditions in the soil.

Octanol/Water Partition Coefficient: No data are available.

Vapor Pressure: The vapor pressure of purified chloroneb $3x10^{-3}$ mm Hg at 25°C.

pH: There are no data available.

Storage Stability: There are no data available.

Flammability: There are no data available.

Oxidizing or Reducing Action: There are no data available.

Explosiveness: There are no data available.

Corrosion Characteristics: There are no data available for technical chloroneb.

Available data on physical and chemical properties of the purified chemical were submitted in tabular form. Methods by which the data were obtained, and individual values were not submitted.

Product Chemistry - Wettable Powder Chloroneb

Data Gaps

1)	Color	163.61-8(c)(1)
2)	Odor	163.61-8(c)(2)
3)	Density or Specific Gravity	163.61-8)c)(8)
4)	pH	163.61-8(c)(11)
5)	Storage Stability	163.61-8(c)(12)
6)	Flammability	163.61-8(c)(13)
7)	Oxidizing or Reducing Action	163.61-8(c)(14)
8)	Explosiveness	163.61-8(c)(15)
9)	Corrosion Characteristics	163.61-8(c)(18)
10)	For each product an analytical method for the determination of chloroneb if produced by an integrated formulation system	163.61-7(a)(3)
11)	Data obtained by use of the above method on representative samples of the product	163.61-7(b)(1)
12)	Declaration and certification of the upper and lower limits for each active ingredient and intentionally added inert ingredient, and the upper limit for each impurtiy, reaction product, and degradation product	163.61-6

Topical Discussions

The product chemistry of chloroneb has been dealt with in the Manufacturing-Use Chloroneb section of this chapter. The following are data required of all wettable powder formulated products of chloroneb.

Active Ingredient Limits in Pesticide Products

For all pesticide products, the Guidelines would require that upper and lower limits be established for each active ingredient, impurity, reaction product, and degradation product. [163.61-5]

Current registrations of wettable powder chloroneb contain 65% a.i.

For no wettable powder formulation of chloroneb has an upper and lower limit been established.

Product Analytical Methods and Data

The Guidelines would require submission of, or reference to, analytical methods measuring each active ingredient in a pesticide product. [163.61-7]

A method for the determination of chloroneb in 65% wettable powder formulations has been submitted (du Pont 1977, 00001444). A sample of the formulated product is slurried with chloroform and filtered through sintered glass. The filtrate is mixed with an internal standard (biphenyl) and aliquots analyzed by gas chromatography on columns of 20% SE-30 on 60-80 mesh Diatoport S. Chloroneb concentration is determined by comparison of the sample area ratio (sample peak area divided by internal standard peak area) to the corresponding ratio determined with a standard solution consisting of chloroneb and biphenyl.

Section 163.61-7 of the Proposed Guidelines would require that applications for registration of pesticide products contain analytical data obtained by methods supplied to the Agency. Data obtained by the method described above have not been submitted.

Section 163.61-7 of the Proposed Guidelines would also require that registrants of formulated products produced by an integrated formulation system (Proposed Guidelines, section 163.61-1) submit methods not only for the active ingredient, but for each identifiable impurity associated with manufacture of the technical chemical. Such methods have not been submitted for any chloroneb formulation.

Physical and Chemical Properties

For every pesticide product, the Proposed Guidelines would require data on certain physical and chemical properties useful for identification purposes or for evaluation of hazard potential [163.61-8].

The following physical and chemical properties are required for all wettable powder products of chloroneb. There are no data except storage stability of Demosan 65W Fungicide (du Pont). Refer to the Confidential Appendix for this storage stability data.

Required Physical/Chemical Properties: Color, odor, density or specific gravity, pH, storage stability, flammability, oxidizing or reducing action, explosiveness, and corrosion characteristics.

Product Chemistry - Granular Chloroneb

Data Gaps

1) Color....................................163.61-8(c)(1)
2) Odor.....................................163.61-8(c)(2)
3) Density or Specific Gravity..............163.61-8)c)(8)
4) pH.......................................163.61-8(c)(11)
5) Storage Stability........................163.61-8(c)(12)
6) Flammability.............................163.61-8(c)(13)
7) Oxidizing or Reducing Action.....................................163.61-8(c)(14)
8) Explosiveness............................163.61-8(c)(15)
9) Corrosion Characteristics................163.61-8(c)(18)
10) For each product an analytical method for the determination of chloroneb if produced by an integrated formulation system.................................163.61-7(a)(3)(4)
11) Data obtained by use of the above method on representative samples of the product..............................163.61-7(b)(1)
12) Declaration and certification of the upper and lower limits for each active ingredient and intentionally added inert ingredient, and the upper limit for each impurtiy, reaction product, and degradation product..................................163.61-6

Topical Discussions

The product chemistry of chloroneb per se has been dealt with in the Manufacturing-use Chloroneb section of this chapter. The following are data required of all granular formulated products of chloroneb.

Active Ingredient Limits in Pesticide Products

For all pesticide products, the Guidelines would require that upper and lower limits be established for each active ingredient, impurity, reaction product, and degradation product. [163.61-5]

Current federal reoistrations of granular chloroneb contain 6.25% to 10% a.i.

For no granular formulation of chloroneb has an upper and lower limit been established.

Product Analytical Methods and Data

The Guidelines would require submission of, or reference to, analytical methods measuring each active ingredient in a pesticide product. [163.61-7]

Section 163.61-7 of the Proposed Guidelines would require that applications for registration of pesticide products contain analytical data obtained by methods supplied to the Agency.

Section 163.61-7 of the Proposed Guidelines would also require that registrants of formulated products produced by an integrated formulation system (Proposed Guidelines, section 163.61-1) submit methods not only for the active ingredient, but for each identifiable impurity associated with manufacture of the technical chemical. Such methods have not been submitted for any chloroneb formulation.

Methods for the determination of chloroneb in granular formulations have not been submitted.

Physical and Chemical Properties

For every pesticide product, the Proposed Guidelines would require data on certain physical and chemical properties useful for identification purposes or for evaluation of hazard potential [163.61-8].

The following physical and chemical properties are required for all granular products of chloroneb. There are no data.

Required Physical/Chemical Properties: Color, odor, density or specific gravity, pH, storage stability, flammability, oxidizing or reducing action, explosiveness, and corrosion characteristics.

Product Chemistry - Dust Chloroneb

Data Gaps

1) Color	163.61-8(c)(1)
2) Odor	163.61-8(c)(2)
3) Density or Specific Gravity	163.61-8(c)(8)
4) pH	163.61-8(c)(11)
5) Storage Stability	163.61-8(c)(12)
6) Flammability	163.61-8(c)(13)
7) Oxidizing or Reducing Action	163.61-8(c)(14)
8) Explosiveness	163.61-8(c)(15)
9) Corrosion Characteristics	163.61-8(c)(18)

10) For each product an analytical method for the determination of chloroneb if produced by an inegrated formulation system............163.61-7(a)(3),(4)
11) Data obtained by use of the above method on representative samples of the product........................163.61-7(b)(1)
12) Declaration and certification of the upper and lower limits for each active ingredient and intentionally added inert ingredient, and the upper limit for each impurtiy, reaction product, and degradation product.................................163.61-6

Topical Discussions

The product chemistry of chloroneb per se has been dealt with in the Manufacturing-use Chloroneb section of this chapter. The following is data required of all dust formulated products of chloroneb.

Active Ingredient Limits in Pesticide Products

For all pesticide products, the Guidelines require that upper and lower limits be established for each active ingredient, impurity, reaction product, and degradation product. [163.61-5]

Current registrations of dust chloroneb contain 10% a.i.

For no dust formulation of chloroneb has an upper and lower limit been established.

Product Analytical Methods and Data

The Guidelines require submission of, or reference to, analytical methods measuring each active ingredient in a pesticide product. [163.61-7]

Section 163.61-7 of the Proposed Guidelines would require that applications for registration of pesticide products contain analytical data obtained by methods supplied to the Agency.

Section 163.61-7 of the Proposed Guidelines would also require that registrants of formulated products produced by an integrated formulation system (Proposed Guidelines, section 163.61-1) submit methods not only for the active ingredient, but for each identifiable impurity associated with manufacture of the technical chemical. Such methods have not been submitted for any chloroneb formulation.

Methods for the determination of chloroneb in dust formulations have not been submitted or cited.

Physical and Chemical Properties

For every pesticide product, the Proposed Guidelines require data on certain physical and chemical properties useful for identification purposes or for evaluation of hazard potential [163.61-8].

The following physical and chemical properties are required for all dust products of chloroneb.

Required Physical/Chemical Properties: Color, odor, density or specific gravity, pH, storage stability, flammability, oxidizing or reducing action, explosiveness, and corrosion characteristics.

Bibliography

Manufacturing-Use

-MRID	CITATION
GS0007-015	Alvarez, J.R., inventor; E.I. du Pont de Nemours and Co., assignee (1968) Process for Preparing 1,4 dichloro-2,5-dimethosybenzene US. patent 3,363,005, Jan. 9
00001428	E.I. duPont de Nemours & Company, Incorporated (1967) Name, Chemical Identity, and Composition: Chloroneb. (Unpublished study received Oct. 16, 1967 under 8F0657; CDL:092951-F)
00001444	E.I. duPont de Nemours & Company, Incorporated (1977) "Demosan" 65W Fungicide: Product Chemistry. Includes method dated October 15, 1976 and undated method. (Unpublished study received May 27, 1977 under 352-312; CDL:232274-A)
05013181	Haglid, F.R., inventor; E.I. duPont de Nemours and Co., assignee (1979) Process for preparing 1,4-dichloro-2,5-dimethoxybenzene, U.S. patent 4,159,391. Jun 26. 3 p. Int. CL 2 C 07C 41/001 U.S. Cl. 568/649
GS007-009	Scribner, R.M.; Soboczenski, E.J.; inventor; (1966) Methods for Protecting Plants and Seeds from Fungi. United States plant patent 3,265,564. Aug 9

Bibliography

Wettable Powder

00001444	E.I. duPont de Nemours & Company, Incorporated (1977) "Demosan" 65W Fungicide: Product Chemistry. Includes method dated Oct. 15, 1976 and undated method. (Unpublished study received May 27, 1977 under 352-312; CDL:232274-A) 0000 1444

IV. ENVIRONMENTAL FATE

A. Use Profile

Chloroneb is a fungicide registered for control of:
1. damping-off and seedling blight of cotton, beans, soybeans, and sugarbeets caused by *Pythium* spp.; 2. soreshin of cotton caused by *Sclerotium rolfsii*; and 3. *Pythium* blight and grey snow mold (*Typhula* spp.) of turfgrass.

Chloroneb is formulated as a 65% active ingredient wettable powder, 10% active ingredient dust, or 1.015-10% active ingredient granulars. The wettable powder is registered for use as a slurry seed treatment or in-furrow spray on cotton, beans, and soybeans and as a slurry seed treatment on sugarbeets. The wettable powder is also registered as a foliar spray on turfgrass. The dust formulation is registered as a planter box seed treatment or in-furrow application on cotton, beans, and soybeans. The granular formulations are registered as in-furrow applications on cotton, beans, and soybeans or as a foliar application on turfgrass.

On turfgrass applications can be made to 5-7 day intervals for *Pythium* blight control on established turf and 7-10 day intervals on new seedings. Applications to turf for snow mold control can be made prior to the first heavy snowfall, during a midwinter thaw, and in early spring as snow is melting. Seed treatments and in-furrow applications on other sites are made at planting.

The major use sites for chloroneb are cotton and turf. Use is less extensive on sugarbeets, beans, and soybeans.

On the order of 500,000 pounds of active ingredient are produced yearly. Of that, the majority of active ingredient is used on cotton and turf. Use on sugarbeets, beans, and soybeans is less extensive.

Registered application rates are listed in Table 1.

B. Environmental Fate - Manufacturing-Use Chloroneb

Environmental Fate Profile

Chloroneb is very resistant to hydrolysis, with no detectable hydrolysis of either the manufacturing-use chemical or the 65% wettable powder formulation occurring over 30 days at an environmental pH range of 5 to 9, and temperatures of 25^{o} and $35^{o}C$.

Table 1. Registered application rates of chloroneb.

Formulation	Site	Type of Application	Application rate (lb. or oz. a.i.)
Dust (10%)	cotton	seed furrow	.5 lb/100 lb seed 1-2 lb/A
	beans	seed furrow	.2 lb/100 lb seed 1 lb/A
	soybeans	seed furrow	.2 lb seed 1 lb/A
Granular (1.015-10%)	turf	foliar	7.1-16.6 lb/A
	cotton	furrow	1-2 lb/A
	beans	furrow	1 lb/A
	soybeans	furrow	1 lb/A
Wettable Powder (65%)	cotton	seed	3.9 oz/100 lb seed[1] 6.5 oz/100 lb seed[2]
		furrow	1.3-1.9 lb/A
	sugarbeets	seed	3.9 oz/100 lb seed
	beans	seed furrow	2.6 oz/100 lb seed .98 lb/A
	soybeans	seed furrow	2.6 oz/100 lb seed .98 lb/A
	turf	foliar	7.08 lb/A[3] 10.6-15.9 lb/A[4]

[1] East of the Rocky Mountains
[2] West of the Rocky Mountains
[3] *Pythium*
[4] Snow mold

Several common soil fungi are capable of transforming chloroneb to 2,5-dichloro-4-methoxyphenol (DCMP) *in vitro*. Of the 20 soil fungi studied, 12 were able to transform up to 60% of chloroneb to DCMP within 10 days in a chloroneb-amended medium (5 g/ml) basal medium. The most active species included *Fusarium solani*, *Sclerotina sclerotiorum*, *Mucor ramannianus*, and *Helminthosporium victoriae*. In addition, 10 of the species studied were capable of converting DCMP to chloroneb. This indicates that dissipation of chloroneb may not be a simple function of conversion to DCMP. The growth of several of the fungi in the above metabolic survey was reduced 10-50% relative to controls, confirming the fungicidal action of chloroneb.

Chloroneb at concentrations of 0.1 to 7.0 ppm had no effect on the growth of effluent microorganisms in a model activated sludge unit. At higher chloroneb levels (70 and 100 ppm), the system became overloaded with insoluble chloroneb, and microbial populations were reduced to 10-20% of control levels. After an acclimation period, sludge microorganisms readily metabolized 40-50% of the applied ^{14}C-chloroneb to $^{14}CO_2$ within 3 weeks of the initial treatment. The chloroneb metabolites DCMP and 2,5-dichlorohydroquinone were recovered from the effluent and accounted for 89% and 4%, respectively, of the effluent radioactivity at day 16 of the study. At day 19, however, the relative proportion of metabolite in the effluent declined, with 47% of the radioactivity present in the form of unchanged chloroneb, even though no change in chloroneb initial concentration had occurred. The degradates are believed to be intermediates in the total degradation of chloroneb.

Therefore, it appears that under moderate chloroneb concentration (7.0 ppm or less) an activated sludge system is capable of degrading the majority of introduced chloroneb. However, the inhibition seen at higher concentrations could pose problems in the event that manufacturing-use chloroneb is discharged directly into an activated sludge treatment system, since chloroneb acting alone in high concentrations or in concert with other discharged chemicals could have an adverse effect on the treatment process.

In a preliminary investigation on the field dissipation of ring-labeled [^{14}C] chloroneb, 48% of the applied radioactivity was lost from the soil within a 3 month period following an application of 2 lb/acre to a Delaware soil. Only 21% of the ^{14}C in the soil was extractable. This extractable material was identified as chloroneb. Therefore, there is a possibility that a portion of the chloroneb or its metabolite(s) forms a bound residue in the soil. Since no free degradation products were noted, it is possible that the observed dissipation of ^{14}C-labelled material was due to movement of chloroneb or its degradates (including $^{14}CO_2$) away from application sites by volatilization or leaching.

In summary, although there is insufficient information to form a comprehensive profile of the fate of chloroneb in the environment, the information available suggests that, under some circumstances, chloroneb may present a persistence problem. Chloroneb does not hydrolyze to a measurable degree under environmental conditions, which could enhance its persistence if entry into aquatic environments occurs. Although chloroneb can be converted to a number of degradation products by certain soil fungi and by activated sludge microorganisms, the rates of these processes are relatively slow. In fact, in the case of an activated sludge system, a substantial portion of the introduced chemical may escape the system undegraded.

The fate and effects of the various phenolic degradates are unknown, and the observed ability of some fungi to reconvert degradation products to chloroneb by methylation has to be considered in predicting the long term fate of the chemical. Also, although there are data indicating that chloroneb dissipates slowly in soil, there is no evidence to indicate what percentage of the dissipation is the result of degradation by soil microorganisms, or is due rather to physico-chemical mechanisms or movement from the application site. The relatively slow rate of dissipation observed raises the possibility that chloroneb residues may accumulate in soil if applications are frequently repeated.

Exposure Profile (Manufacturing-Use Chloroneb)

Because of the scarcity of data on the environmental presence or fate of chloroneb, it is impossible to quantitatively assess exposure of human and wildlife to manufacturing-use chloroneb. However, provided that chloroneb enters waterways as a result of manufacture, a potential for food-chain accumulation of chloroneb and subsequent human and wildlife exposure may be dictated by the low solubility of chloroneb in water (8 ppm).

Data Gaps

To support the registration of all formulated chloroneb products, it is necessary to submit or cite the following data:

Food Use (Terrestrial Field-Vegetable Crop)

Photodegradation studies	163.62-7(c)
Soil metabolism studies-aerobic and anaerobic	163.62-8(b,c)
Metabolism studies-effects of microbes on chloroneb except fungi	163.62-8(f)(2)
Metabolism studies-effects of chloroneb on microbes	163.62-8(f)(3)
Leaching and adsorption/desorption studies	163.62-9(b,d)
Terrestrial Field Dissipation studies	163.62-10(b)(1,4)
Rotational Crop and Fish Accumulation studies	163.62-11(b,d)

Nonfood Use (Terrestrial Noncrop)

All above environmental fate topics are required except Anaerobic soil metabolism (163.62-8(c) and Rotational Crop studies (163.62-11(b).

Topical Discussions

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines for Registering Pesticides' in the United States (43 FR 29696, July 10, 1978) which explains the minimum data that the Agency requires in order to adequately assess a pesticide's Environmental Fate.

All topics related to the Environmental Fate of chloroneb as an active ingredient are discussed under Manufacturing-Use Chloroneb.

	Guidelines Section
Physico-Chemical Transformation	163.62-7
Metabolism (Soil, Aquatic and Microbiological)	163.63-8
Mobility	163.62-9
Field Dissipation	163.62-10
Accumulation	163.62-11

PHYSICO-CHEMICAL TRANSFORMATION 163.62-7

Hydrolysis

Hydrolysis data are required to support the registration of all manufacturing-use products regardless of the intended end uses of products formulated from the manufacturing-use product.

Data from a single study (Harvey 1979, GS0007-6) indicate that chloroneb will not hydrolyze under typical environmental conditions. No chloroneb degradation products were identified by high-pressure liquid chromatography within 30 days when $[^{14}C]$chloroneb (4 ppm) was maintained in distilled water or at buffered pH 5-7 and 25 or 35 C. No hydrolysis products were detected when a 650 ppm aqueous solution of a chloroneb formulation (Tersan SP, 65% chloroneb) was maintained under the same conditions. Similarly, no degradation was observed when the same chloroneb formulation was maintained in acid (0.1 N HCl) or base (0.1 N NaOH) for 44 hours.

This study is adequate to assess chloroneb hydrolysis and fulfill the data requirements in Section 163.62-7(b) of EPA's Proposed Guidelines for Registering Pesticides (July 1978). No data gaps were identified.

Photolysis

Photodegradation studies in water are required to support the registration of all formulated chloroneb products intended for terrestrial uses.

Studies in soil are required to support the registration of all chloroneb formulated products intended for crop uses.

No data on the photolysis of chloroneb are available.

All data specified in Section 163.62-7(c) are needed to determine the effect of light on chloroneb.

METABOLISM 163.62-8

Data on metabolism are required to determine the nature of pesticide residues and their availability to rotational crops, and to help in the assessment of potential disposal and reentry hazards.

Soil Metabolism

Aerobic metabolism studies are required to support the registration of all formulated chloroneb products intended for terrestrial uses. Anaerobic soil metabolism studies are required to support the registration of all formulated products intended for field and vegetable crop uses.

No data on the metabolism of chloroneb in soil are available.

All data specified in Section 163.62-8(b,c) are needed to determine the metabolism of chloroneb in soil.

Aquatic Metabolism

No data are required on the aquatic metabolism of chloroneb because the use pattern indicates that direct discharge into the aquatic environment is unlikely.

Microbiological Metabolism

Data on the effects of microbes on pesticide degradation and effects of pesticides on microbes are required to support the registration of all chloroneb formulated products intended for terrestrial uses.

Microbiological Metabolism - Effects of Microbes on Pesticides

Two valid studies relating to the effects of microbes on pesticides were reviewed. The first (Hock and Sisler 1969, 05001155) assessed the ability of selected microbes to metabolize $[^{14}\mathrm{C}]$chloroneb within 24 hours. The metabolite 2,5-dichloro-4-methoxyphenol (DCMP) accounted for greater than 50% of the medium radioactivity when *Rhizoctonia solani* was incubated in the presence of either methyl-or ring-labeled $[^{14}\mathrm{C}]$chloroneb at 5, 8, or 15 μg/ml for 24 hours. When *Neurospora crassa* conidia were cultured with $[^{14}\mathrm{C}]$chloroneb at 16 g/ml, an unidentified metabolite (not quantified) was produced. Neither *Sclerotium rolfsii* nor *Saccharomyces pastorianus* was capable of metabolizing chloroneb within 24 hours.

In a study by Wiese and Vargas (1973, 05001170), 13 of 23 soil microorganism species were able to convert some of the chloroneb to DCMP within 10 days in a chloroneb-amended (5 μg/ml) basal medium. Other unidentified components, possibly impurities or other degradation products, were detected but not quantified in extracts of cellular material and culture media. In an attempt to determine if DCMP would be further metabolized to 2,5-dichlorohydroquinone (DCHQ) via a second demethylation, it was discovered that 10 species are capable of resynthesizing chloroneb from DCMP.

In contrast to the findings of Hock and Sisler (1969, 05001155), this study demonstrated that *R. solani* could neither grow in media containing chloroneb at 5 μg/ml nor metabolize the chloroneb to DCMP. This discrepancy may be due to different incubation conditions which were employed in the two studies. Hock and Sisler used stationary mycelial mats, whereas Wiese and Vargas incubated their culture on a shaker. Using such a technique, they were able to demonstrate that although growth of the organism is inhibited by chloroneb, mature hyphae possess the capability to degrade this compound.

These studies show that several common soil microorganisms species are capable of degrading chloroneb to DCMP in vitro. Some soil microbes are also capable of resynthesizing chloroneb from DCMP. Therefore, the rate of chloroneb degradation in soil will be related to the relative populations of microorganism species capable of degrading or resynthesizing chloroneb.

It can be concluded from these studies that many soil fungi are capable of demethylating chloroneb to DCMP and degrading chloroneb to other unidentified degradation products.

Additional studies are needed using the procedures outlined in Section 163.62-8(f)(2) to determine the effects of bacteria and algae on chloroneb.

Microbiological Metabolism - Effects of Pesticides on Microbes

Four valid studies were reviewed. Wiese and Vargas (1973, 05001170) observed that growth of *R. solani* was completely inhibited by chloroneb at 5 µg/ml. Growth of several other fungal species was also reduced 10-50% in the presence of chloroneb at low concentrations.

Studies by Kappas (1978, 05001167) and Georgopoulos et al. (1976, 05001308) showed that chloroneb inhibits the growth of *Aspergillus nidulans*. At 20-40 M chloroneb, the former investigator observed 30-61% growth inhibition in complete media over 3 days, whereas the latter investigators observed a 36-67% growth inhibition at 24-38 µM in complete media over 5 days. Azevedo et al. (1977, 05001292) also observed drastic growth inhibition by chloroneb in chloroneb-sensitive strains of *A. nidulans* at 50 ppm, while 400 ppm was required to inhibit growth of resistant strains. The frequency of mitotic recombination was increased and haploidization of a diploid strain was decreased, as well. Under very limited conditions and species, chloroneb is capable of affecting growth and genetic characteristics of microbes.

All data specified in Section 163.62-8(f)(3) are needed to determine the effects of chloroneb on microorganisms.

Activated Sludge Metabolism

A laboratory study of the effects of pesticides on the wastewater treatment process is required to support the registration of all manufacturing-use products and all formulated products that are indirectly discharged into wastewater treatment systems or are used as treatments in wastewater treatment systems.

Harvey (1979, GS0007-7) studied the fate and effects of [^{14}C]chloroneb in a simulated wastewater treatment system. Chloroneb added daily for 29 days to a closed aerated system in increments between 0.1 and 100 ppm had no effect (determined by plate counts) on the growth of effluent microorganisms at concentrations of 7 ppm or less. AT 70 ppm or above, the system became overloaded with insoluble chloroneb and colony sizes were 10-20% of control levels. After a lag period of about 10 days, sludge microorganisms readily metabolized the applied chloroneb. Approximately 40-45% of the chloroneb applied daily was metabolized to $^{14}CO_2$ after 3 weeks. High-pressure liquid chromatography of the effluent sampled identified two metabolites, 2,5-dichloro-4-methoxyphenol (DCMP) and 2,5-dichlorohydroquinone (DCHQ), which reached maximum concentrations, respectively, of 89 and 4% of the effluent radioactivity, respectively, on the 16th day of the study.

This study is considered adequate to assess the effects and fate of chloroneb in waste treatment facilities as specified in Section 163.62-8(g). No data gaps were identified.

MOBILITY 163.62-9

Data on mobility are required to determine pesticide residue movement in the environment.

Leaching

Leaching data are required to support registration of formulated products intended for terrestrial noncrop and field/vegetable crop uses.

All data specified in Section 163.62-9(b) are needed to determine the susceptibility of chloroneb to leaching.

Volatility

No data are required on the volatility of chloroneb because the use pattern of chloroneb does not include a greenhouse use.

Adsorption/Desorption

A laboratory study using radioisotopic or nonradioisotopic analytical techniques is required to support the registration of all chloroneb formulated products intended for terrestrial uses.

No valid data on the adsorption/desorption of chloroneb are available.

All data specified in Section 163.62-9(d) are needed to determine the adsorption/desorption of chloroneb.

Water Dispersal

No data are required on the water dispersal of chloroneb because the use pattern indicates that direct introduction into the aquatic environment is unlikely to occur.

FIELD DISSIPATION 163.62-10

A field dissipation study using representative formulations under actual use conditions is required to support the registration of all chloroneb formulated products intended for terrestrial uses.

Terrestrial

The study reviewed below provides preliminary data on terrestrial field dissipation of chloroneb.

Rhodes (1968, 00001426) studied the dissipation of ring-labeled [^{14}C]-chloroneb in a Delaware soil. At various sampling intervals up to 6 months following application (2 lb ai/A), the soils were Soxhlet extracted with acetone and the extracts were analyzed by thin-layer chromatography. The extractable ^{14}C (about 21% of ^{14}C present at 3 months) was identified as chloroneb. No free chloroneb degradation products were observed within a depth of 1-3 inches. Approximately 28% of the applied radioactivity dissipated from the soil by 1 month following application. Further loss of radioactivity from the soil continued over the next 2 months. However, the remaining 52% of radioactivity showed no further decline. No loss of radioactivity was detectable during the 3-6 month interval; this may be partially attributed to the fact that the earth was frozen, creating unfavorable conditions for chloroneb dissipation. Most of the recovered radioactivity remained within the 1-3 inch soil depth throughout the experiment.

Additional studies are needed as specified in Section 163.62-10(b) in the following areas:

- Four studies in field and vegetable crop use areas using granular and wettable powder formulations of chloroneb as specified in Section 163.62-10(b)(1)

- Two studies in turf use areas using granular and wettable powder formulations of chloroneb as specified in Section 163.62-10(b)(4)

Aquatic Dissipation

No data are required on the aquatic dissipation of chloroneb because the use pattern indicates that direct introduction into the aquatic environment is unlikely to occur.

Terrestrial/Aquatic (Forest)

No data are required on the terrestrial/aquatic dissipation of chloroneb because the use pattern indicates that direct introduction into a forest environment is unlikely to occur.

Aquatic Impact Uses

No data are required on the aquatic impact of chloroneb because the use pattern indicates that direct introduction into the aquatic environment is unlikely to occur.

ACCUMULATION 163.62-11

Data on accumulation are required to determine accumulation in food webs.

Rotational Crops

Rotational crop studies are required to support the registration of all chloroneb formulated products intended for field/ vegetable uses.

No data on the accumulation of chloroneb in rotational crops are available.

All data specified in Section 163.62-11(b) are needed to determine the accumulation of chloroneb (granular and wettable powder) in rotational crops.

Irrigated Crops

No data are required on the accumulation of chloroneb in irrigated crops because the use pattern indicates that chloroneb is not used on irrigated crops.

Fish

This laboratory study employing radioisotopic or nonradioisotopic analytical techniques is required to support the registration of all chloroneb formulated products intended for terrestrial noncrop and field/vegetable crop uses.

No data on the accumulation of chloroneb in fish are available.

All data specified in Section 163.62-11(d) are needed to determine the accumulation of chloroneb in fish.

Formulated Chloroneb - Exposure Profile

All Formulations

The relatively high vapor pressure of chloroneb creates the potential of exposure by inhalation of the volatilized chemical in all its formulations. Chloroneb formulations are not applied aerially, thereby greatly reducing the possibilities for contamination of persons, livestock, and wildlife outside of application sites. Because soil mobility data are lacking, the potential exposure of humans to chloroneb through contamination of drinking water cannot be assessed. For the same reason, the potential for exposure of aquatic organisms is unknown.

Dissipation of chloroneb in soil cannot be assumed to eliminate use-associated hazards because chlorophenols are major products of soil microbial metabolism of chloroneb.

The principal sites of usage of chloroneb appear to be cotton and turf (predominantly golf-courses), and the principal regions of exposure are expected to be the Mid-West and the cotton belt.

Wettable Powder Formulations

Inhalation of volatilized chloroneb may be considerable in view of its relatively high vapor pressure. This may be particularly true for the turf treatment use of chloroneb 65% wettable powder on golf course fairways and greens where weekly treatments of 7 lb. a.i. per acre may be used.

Significant human exposure may also occur by dermal or ocular routes from splashing during the dilution, tank-mixing, and loading of spray equipment with the wettable powder. Exposure of applicators by breathing of spray droplets could be important for these formulations.

Granular Formulations

No significant exposures to humans which are unique to the granular formulations are foreseen. Availability of granular chloroneb may differ from other formulations to terrestrial wildlife and birds.

Dust Formulations

Inhalation of a dust formulation or dermal contact with it are the primary routes of exposure.

Bibliography

-MRID	CITATION
05001292	Azevedo, J.L., E.P. Santana, and R. Bonatelli, Jr. 1977. Resistance and mitotic instability to chloroneb and 1,4-oxathiin in *Aspergillus nidulans*. Mutation Res. *48(2):163-172*
05001308	Georgopoulos, S.G., A. Kappas, and A.C. Hastie. 1976. Induced sectoring in diploid *Aspergillus nidulans* as a criterion of fungitoxicity by interference with hereditary processes. Phytopath. 66(2):217-220
GS0007-006	Harvey, J. 1979. Stability of [^{14}C]chloroneb in water at various pH values. (Unpublished study received Dec. 13, 1979, under 352-GIA; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del. CDL:241500.)
GS0007-007	Harvey, J. 1979. Activated sewage sludge metabolism of [^{14}C]chloroneb. (Unpublished study received Dec. 13, 1979, under 352-GIA; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del. CDL:241500.)
05001155	Hock, W.K., and H.D. Sisler. 1969. Metabolism of chloroneb by *Rhizoctonia solani* and other fungi. J. *Agri. Food Chem.* 17(1):123-128
05001167	Kappas, A. 1978. On the mechanisms of induced somatic recombination by certain fungicides in *Aspergillus hidulans*. Mutation Res. *51(2):189-197*
00001426	Rhodes, R.C. 1968. Disappearance of ^{14}C-ring-labeled chloroneb from soil. (Unpublished study received July 8, 1968, under 8F0657; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del. CDL:091147-J.)
05001170	Wiese, M.V., and J.M. Vargas, Jr. 1973. Interconversion of chloroneb and 2,5-dichloro-4-methoxyphenol by soil microorganisms. Pesticide Biochem. Physiol. 3(2):214-222.

V. TOXICOLOGY

Toxicology - Manufacturing-Use Chloroneb

Toxicology Profile

The high acute oral LD_{50} of 90% technical chloroneb in rats (greater than 5 g/kg) suggests a very low acute oral hazard to human beings. Gross changes included heavy livers (in two of five females) and kidneys with hydronephrosis (in two of five males). Based on the high 4-hour LC_{50} (25.2 mg/liter) in male rats, a low acute inhalation hazard in human beings is expected, pending receipt of data on female rats. Technical chloroneb (90%) is not expected to irritate human eyes, based on studies conducted with rabbits. No eye irritation was noted when this compound was instilled into rabbit eyes. Technical chloroneb (90%) has a low potential for primary dermal irritation in human beings. It was only slightly irritating to rabbit skin.

No subchronic dermal, subchronic oral, or chronic feeding studies are available on the technical product. Adequate subchronic tests are available on 65 and 75% wettable powder formulations, which contained 90 or 98% pure chloroneb, respectively. Presently, these satisfy Agency requirements for the technical product. The known chloroneb impurities or inert formulation ingredients should not significantly affect the toxicity of the active ingredient. Nor should extrapolation of results underestimate hazard to human beings or to domestic animals.

In general, new toxicologic studies might be required if the Agency determines that previously uncharacterized, toxic impurities are present in techical chloroneb. Chlorinated dibenzodioxins, theoretically, could be present. A detailed description of chemicals present in any technical chloroneb used as a test substance, therefore, it necessary for realistic evaluation of key chloroneb toxicologic studies (including subchronic and chronic). Likewise, new toxicologic information may be needed should unknown or inadequately tested chloroneb metabolites be found in pesticide residues in treated foods or feeds or food animals.

Repeated application of technical chloroneb to human skin may not result in systemic effects, based on results of a subchronic dermal test on a 75% wettable powder formulation of chloroneb. In rabbits, subchronic dermal application of as much as 5 g/kg (as active ingredient) did not result in observed clinical or pathological change, except for a slightly lower weight gain.

Data from subchronic and chronic oral studies on 65 or 75% wettable powder formulations of chloroneb indicate that high oral doses of technical chloroneb primarily affect the liver, kidney, stomach, and thyroid.

Ninety-day feeding of the 65 or 75% wettable powder in rats resulted in increased weight of the liver and kidney and histopathologic changes in these organs. The observed increased urine sugar supports the findings of kidney damage. The "no-observed effect level" (NOEL) for the study is 500 ppm.

Two-year feeding to dogs of 2,500-10,000 ppm resulted (as 65 or 75% wettable powders) in gastritis and in pathological alterations and weight increases in the liver. The elevated Scrum glutamic-pyruvic transaminase activity (SGPT) seen at 18 months, supports the finding of liver damage. Liver damage was not noted in rats fed up to 2,500 ppm chloroneb for 2 years. Morphologic changes in the thyroid were noted in rats at 1 year and dogs at 2 years, indicating a moderate increase in activity. The kidney was not affected in these studies in either rat or dog. The high levels of chloroneb intake also caused reduced body-weight gain in rats and weight loss in dogs. For these 2-year studies, the NOEL is 500 ppm for both dog and rat. These NOEL's correspond to 12.5 mg/kg body weight/day of chloroneb for the dog and 25 mg/kg body weight/day of chloroneb for the rat. The dog study meets Agency requirements for a non-rodent subchronic feeding study.

A final judgment as to adequacy of this rat study as a chronic feeding study cannot be made until detailed chemical characterization of the test substances (technical chloronebs 90 and 98% pure) is provided. In addition to this requirement, further information and classification of neoplastic and non-neoplastic lesions found in the study must be provided before it can be evaluated for acceptability as an oncogenicity study.

To assess oncogenic potential, an oncogenicity test in an acceptable mammalian species other than the rat is needed. As noted above, a new oncogenicity study may be needed in the rat.

Chloroneb has not been evaluated for mutagenicity. Acceptable mutagenicity tests (see Guidelines of August 22, 1978, 40 FR Part 163) must be submitted or cited to support registration of any proposed end-use. Because of possible exposure of women of child-bearing age, teratogenicity studies in two species are needed to support all existing end-uses.

Limited tissue residue data indicate that both chloroneb and a metabolite, 2,5-dichloro-4-methoxyphenol, show a very low order of bioaccumulation in mammalian tissues after long-term dietary exposure to chloroneb. In rats and dogs fed chloroneb (as a 65 or 75% wettable powder) for 2 years, the parent compound occurred primarily in body fat, and the metabolite occurred chiefly in liver and kidney. Dogs eliminate the metabolite in urine and, to a lesser extent, in feces. The metabolite also occurs in rat urine. Rats feces were not analyzed. To fulfill Agency requirements on metabolism, single-dose testing of chloroneb is required. The available data are insufficient to assess the mammalian metabolism of chloroneb.

Additional tests that must be conducted to assess the toxicity of technical chloroneb are listed in the section on Data Gaps.

Data Requirements

The following are toxicology data requirements. Listed after each requirement is the section in the Proposed Guidelines of August 22, 1978, (43 FR, No. 163 37336) that describes the type of data required.

All applicants, regardless of end-use, must submit or cite the following data:

Category of Test	Guideline Number
Acute Oral Toxicity (rat)	163.81-1
Acute Dermal Toxicity (rabbit)	163.81-2
Acute Inhalation Toxicity (rat)	163.81-3
Primary Eye Irritation (rabbit)	163.81-4
or Demonstration of pH 1-3 or 12-14	
or Demonstration of Dermal Irritation of Category I	
Primary Dermal Irritation (rabbit)	163.81-5
Skin Sensitization (guinea pig)	163.81-6

Data Gaps

The following data are required for the reregistration of manufacturing-use chloroneb:

Acute Toxicity

Acute Dermal Toxicity	163.81-2
Acute Inhalation Toxicity (Female Rats)	163.81-3
Skin Sensitization	163.81-6

Food Use (Requires a Tolerance or Exemption)

All applicants for registration or reregistration of technical products which are formulated into end-use products intended for use on food must submit or cite the following:

Chronic Feeding	A two year feeding study in the rat is required. The available rat study is inadequate, pending evaluation of the chemical composition of technical chloroneb, including minor impurities.	163.83-1
Oncogenicity	An oncogenicity study in each of two suitable mammalian species is required. Registrants may cite the referenced two-year rat study provided that they also submit the appropriate supplementary data.	163.83-2
Teratogenicity	Teratogenicity testing in two mammalian species is required.	163.83-3
Reproduction	A two-generation reproduction study, preferably in the rat is required. A summarized reproduction study is in Agency files.	163.83-4
Mutagenicity	A mammalian in vitro point mutation test; a sensitive sub-mammalian point mutation test; a primary DNA damage test; a mammalian in vitro cytogenetics test.	163.81-1 through 163.81-4
Metabolism	A general metabolism study in one mammalian species is required.	163.85-1

Non-Food Use (Nondomestic, Outdoor)

All applicants for registration or reregistration of technical products which are formulated into end-use products intended for non-food, nondomestic, outdoor uses must submit or cite the following:

Teratogeniticy	Teratogenicity testing in two mammalian species is required.	163.83.3
Mutagenicity	A mammalian *in vitro* point mutation test; a sensitive sub-mammalian point mutation test; a primary DNA damage test; a mammalian *in vitro* cytogenetics test.	163.83-1 through 163.83-4

Human and Domestic Animal Hazard Assessment

The chloroneb exposure profile (see Exposure Profile in the Environmental Fate Chapter) reveals that persons who handle, store, or ship technical chloroneb will be exposed, principally, by inhalation. Without taking proper precautions, they may get it on the skin and in the eyes.

Single exposure by any of these routes to technical chloroneb may be of low hazard. Technical chloroneb (90%) showed relatively high acute inhalation toxicity (tested in males, only). Applied once to skin or eyes, it caused little or no primary irritation. Limited skin application may not cause systemic hazard; since, on repeated, daily skin contact with large doses of chloroneb (as 75% wettable powder), only reduced body-weight gain was noted. Swallowing a lethal dose of technical chloroneb by accident seems unlikely, based on the relatively high acute oral LD50 shown by technical chloroneb (90%).

Required Labeling

Precautionary labeling of each product must correspond to the toxicity categories determined by five acute toxicity tests. Acceptable categories of acute toxicity and the corresponding required labeling appear in the Regulatory Chapter of this Standard.

Topical Discussions

Corresponding to each of the Topical Discussions listed below is the number of the section(s) in the 'Proposed Guidelines' of August 22, 1978 (43 FR, No. 163 37336 which explain(s) the minimum data that the Agency usually requires in order to adequately assess chloroneb's toxicology. Where no section number is listed, a minimum requirement has not been set for such information. Also under each of the topics is a reference to the section in the 'Proposed Guidelines'.

Acute Testing	Guidelines Section(s)
Acute Oral Toxicity	163.81-1
Acute Dermal Toxicity	163.81-2
Acute Inhalation Toxicity	163.81-3
Primary Eye Irritation	163.81-4
Primary Dermal Irritation	163.81-5
Skin Sensitization	163.81-6
Acute Delayed Neurotoxicity	163.81-7
Subchronic Testing	
Subchronic Oral Toxicity	163.82-1
Subchronic 21-Day Dermal Toxicity	163.82-2
Subchronic 90-Day Dermal Toxicity	163.82-3
Subchronic Inhalation Toxicity	163.82-4
Subchronic Neurotoxicity	163-82-5
Dermal Sensitization	163.82-6
Chronic Testing	
Chronic Feeding	163.83-1
Oncogenicity	163.83-2
Reproduction Testing	
Teratology	163.83-3
Reproduction	163.83-4
Mutagenicity	163.83-1 to 4
Metabolism in Laboratory Animals	163.85-1
Clinical Trials	
Emergency Treatment	

The following topical discussions describe available toxicity data on technical chloroneb and its formulations and state whether they are adequate for Agency regulatory purposes.

Acute Testing

Acute Oral Toxicity (163.81-1)

The minimum testing needed on acute oral toxicity is one test, in the laboratory rat, on the technical chemical and on each manufacturing-use product.

The LD_{50} of technical chloroneb (90% active ingredient) exceeds 5 g/kg in male and female rats (Hinckle 1979, GS0007-010). Clinical signs included diarrhea, stained face and perineal area, and weight loss. Gross pathologic changes included heavy liver (two of five females), kidneys with hydronephrosis (two of five males), corneal opacity (one of five males), and lungs that were dull-red, gray mottled with gray foci in one to three animals (not further described). This study is sufficient to assess the acute oral toxicity of technical chloroneb and to place it in Category IV, corresponding to a very low acute oral hazard.

Acute Dermal Toxicity (163.81-2)

The minimum testing needed on acute dermal toxicity is one test, preferably in the albino rabbit, on the technical chemical and on each manufacturing-use product.

No tests on technical chloroneb are available.

Acute Inhalation Toxicity (163.81-3)

The minimum data requirement for acute inhalation toxicity is one test, preferably in the albino rat, on the technical chemical and on each manufacturing-use product.

The 4-hour LC_{50} of chloroneb aerosol (formed from a melt of particulate chloroneb) was 25.2 mg/liter in male rats (Kwon 1965, 00004982). Lethal concentrations resulted in hyperemia, unresponsiveness, mydriasis, and respiratory irregularities. Hyperemia and hyperpnea were observed at sublethal concentrations. This is an adequate determination in males, which would place particulate chloroneb in Category IV, indicating a very low acute inhalation hazard. Testing in females, however, must be conducted to adequately assess inhalation toxicity.

Primary Eye Irritation (163.81-4)

The minimum testing needed to evaluate eye irritation potential is one test, in albino rabbits, on each manufacturing use product. If the test substance has a pH of 1-3 or 12-14, however, it will be judged corrosive, and an eye irritation test is not needed. If the test substance has been judged to be dermally corrosive, an eye irritation test is not needed.

Technical chloroneb (90% active ingredient) was not irritating to the eyes of rabbits (Ferenz 1979a, GS0007-011). Instillation of 0.1 ml (50 mg) of the test product resulted in no corneal opacity, iritis, or conjunctival irritation in either washed or unwashed eyes. The study meets Agency requirements for a primary eye irritation test and is adequate to place this technical chloroneb product in Category IV, indicating a very low eye irritation potential.

Primary Dermal Irritation (163.81-5)

The minimum testing needed to evaluate dermal irritation potential is one test, preferably on the albino rabbit, on each manufacturing use product.

Technical chloroneb (90% active ingredient) was very slightly irritating to intact and abraded rabbit skin at either 24 or 72 hours (Ferenz 1979b, GS0007-012). The study is adequate to place technical chloroneb in Category IV, indicating a very low potential for dermal irritation.

Skin Sensitization (163.81-6)

The minimum requirement for assessing skin sensitization is an interdermal test in one mammalian species, preferably the guinea pig, on each manufacturing-use product.

No testing is available for manufacturing-use chloroneb.

Acute Delayed Neurotoxicity (163.81-7)

An acute delayed neurotoxicity evaluation is not required because chloroneb is not expected to cause acetylcholinesterase depression, nor is its chemical structure related to that of substances that induce delayed neurotoxicity.

Subchronic Testing

Subchronic Oral Toxicity (163.82-1)

The minimum testing needed to assess subchronic oral toxicity is one test in each of two mammalian species, a rodent and a non-rodent, on the technical chemical.

No adequate subchronic oral test of the technical product itself is available. However, a 90-day feeding study in rats on a 75% formulation of chloroneb (Sherman 1964a, 00001446; described below) is judged adequate to fulfill Agency requirements for a rodent study, and a 2-year feeding study in dogs on a 65 or 75% wettable powder (Busey and Kundzins 1967, 00001421, described below) satisfies the requirement for a non-rodent study. tthe known impurities and inerts in the 65 or 75% wettable powder formulations are not expected to decrease the toxicity of technical chloroneb in such studies or correspondingly, to cause underestimation of human hazard.

A summary of a 90-day rat feeding study on a mixture of substances that comprise the impurities (10%) in technical (90%) chloroneb (as determined in 1967) is in Agency files. It will be reviewed when details of the study become available.

In preliminary testing, Sherman (1964b, 00004980) gave each of two male rats technical chloroneb at 3.400 mg/kg body weight/day as a suspension in peanut oil, 5 days a week, for 2 weeks. The only toxic sign was salivation during the second week of dosing.

In a preliminary study, six rats were dosed repeatedly with a wettable powder formulation containing 75% of active ingredient (Sherman 1964b, 00004980). Cumulative oral toxicity was observed in these rats, each of which received orally 5 g/kg body weight/day (based on active ingredient), 5 days a week, for 2 weeks. They lost weight and showed diarrhea during the first week and showed weakness and semi-prostration during the second week. Two of six rats died after eight doses. Pathologic findings included congestion of organs, injury to blood cells and blood-forming organs (spleen and bone marrow), slight injury to kidneys, and large liver with cytoplasmic and nuclear irregularities. The compound appeared to affect the hematopoietic system, liver, and kidneys.

A 90-day feeding study was conducted in rats using a wettable powder formulation containing 75% active ingredient at 0, 50, 500, and 5,000-7,500 ppm (based on the active ingredient) in the diet (Sherman 1964a, 00001446). There was no behavioral, hematologic, or nutritional evidence of toxicity. Increased sugar was present in the urine of male and female rats fed the highest dose. In rats on this dose, the urine sediment contained large numbers of epithelial cells (males) and leukocytes (females). Increased liver and kidney weights in male rats and increased liver weights in female rats were recorded in the highest-dosage groups. Histopathologic examination revealed tubular degeneration in the kidneys and centrilobular enlargement of hepatic cells with unequal hypertrophy of the hepatic cell nuclei in livers of male rats fed the highest dose. The "no-observed-effect level" (NOEL) for the study is 500 ppm (25 mg/kg body weight/day). This study is judged adequate to fulfill Agency requirements for a subchronic rodent study.

In a 2-year feeding study, beagle dogs received chloroneb (as a 65 or 75% wettable powder) in the diet at 0, 100, 500, or 2,500-10,000 ppm of active ingredient (Busey and Kundzins 1967, 00001421). Loss of body weight occurred in dogs in the high-level group when fed 7,500, 8,750, or 10,000 ppm. In three of six high-dose dogs at 18 months, serum glutamic-pyruvic transaminase and/or alkaline phosphatase activities were moderately-to-markedly elevated. At necropsy, the mean and relative liver weights of the high-dose dogs were moderately elevated over those of controls. Histopathologic changes were found in dogs of this group after 2 years on test. Changes in the thyroid, indicative of a moderate increase in activity, were characterized by uniform, small-to-medium-sized follicles that were lined by medium-to-high cuboidal epithelium in four of six dogs. The livers from four of six dogs had moderate-to-severe pigmentation consisting of small yellowish-brown granules in hepatocytes. A moderate subacute-to-chronic catarrhal gastritis was observed in stomachs from four of six dogs.

As judged by appearance, behavior, appetite, elimination, body weight changes, clinical laboratory values, organ weights, organ-weight/body-weight ratios, and gross necropsy and histopathologic findings, chloroneb at either 100 or 500 ppm chloroneb in the diet, fed for 2 years, did not adversely affect these dogs. The NOEL for the study is 500 ppm (12.5 mg/kg body weight/day). This study is judged adequate to comply with the requirement for a non-rodent subchronic oral study.

Subchronic 21-Day Dermal Toxicity (163.82-2)

The minimum requirement to assess subchronic 21-day dermal toxicity is one study preferably in the albino rabbit, on the technical product. This study is required for all uses of chloroneb.

No studies of subchronic dermal toxicity have been conducted using technical chloroneb itself. However, a test on a formulated product (Hood 1965, 00001445, described below) is judged adequate to fulfill Agency requirements for a subchronic dermal test on the technical product.

A study by Hood (1965, 00001445) was conducted on a 75% wettable powder formulation containing 75% active ingredient using groups of five male and five female rabbits. A 55% aqueous paste of the formulation was kept on abraded skin of each rabbit, during each of fifteen, daily 5-hour periods, over 3 weeks, at 5 g/kg body weight (as active ingredient). One control group was untreated. In the other control group, each application of the wettable powder formulation-without-chloroneb was made at 1 g/kg body weight. Except for slightly lower weight gain in test rabbits, there were no apparent effects of chloroneb on clinical signs, organ weights, relative organ weights, or histopathologic findings.

The study is judged adequate to comply with Agency requirements for subchronic 21-day dermal test on the technical product.

Subchronic 90-Day Dermal Toxicity (163.82-3)

A subchronic 90-day dermal toxicity test is not required because chloroneb is not purposely applied to skin, and its use will not result in human exposure comparable to, for example, the exposure of swimmers to swimming pool additives or garment wearers to pesticide-impregnated fabric.

Subchronic Inhalation (163.82-4)

A subchronic inhalation study is required if pesticidal use may result in repeated inhalation exposure at a concentration that is likely to be toxic, as determined from results of acute inhalation testing. Acute inhalation testing on chloroneb is incomplete, so a final determination on the requirement for a subchronic inhalation test cannot be made at this time.

Subchronic Neurotoxicity (163.82-5)

A subchronic neurotoxicity evaluation is not required on chloroneb because it is not expected to induce neuropathy or delayed neurotoxicity, and because it does not have a molecular structure closely related to that of a compound that is known to induce neuropathy or delayed neurotoxicity.

Chronic Testing

Chronic Feeding (163.83)

A chronic feeding study is required for all food uses in one mammalian species, preferably the laboratory rat, using the technical product. The study is required for all food uses of chloroneb.

No chronic tests are available on technical chloroneb. At present, a study in rats on a wettable powder containing 65 or 75% chloroneb (Busey et al. 1967, 00001422, described below) will not satisfy Agency requirements for a chronic test because the test substances are inadequately characterized. The test chemicals were 98 and 90% pure chloroneb, formulated as 75 and 65% wettable powders, respectively. The study cannot be judged for adequacy as a chronic feeding study until the test substances (90 and 98% pure technical chloroneb) have been adequately characterized. This includes the characterization of minor impurities.

In this study, a wettable powder containing 65 or 75% chloroneb was fed to rats at dietary levels of 0, 100, 500, and 2,500 ppm (based on active ingredient) for 2 years (Busey et al. 1967, 00001422). Marked growth suppression and reduced food consumption occurred in the females, and moderate growth suppression occurred in the males given the highest dose. No abnormalities were noted in physical appearance, behavior, or extent of survival in any test group. Hematology, clinical biochemistry, urinalysis, and gross necropsy evaluations did not reveal effects that were judged to be compound-related. In male rats on 2,500 ppm which were killed after 1 year of feeding (but not in those killed after 2 years), there was microscopic evidence of increased thyroid activity. Female rats on 2,500 ppm which were killed at 2 years showed significantly increased organ-weight/ body-weight values for brain and thyroid and decreased spleen weights. The NOEL for the study is 500 ppm (25 mg/kg body weight/day).

Provisionally, the study does not meet Agency requirements for a chronic feeding study. It will be judged for adequacy when the detailed composition of the test chemicals (98 and 90% chloronebs) fed in the study is provided.

Oncogenicity (163.83-2)

Oncogenicity tests using the technical material are required in two mammalian species, normally the rat and the mouse. The studies are required for all food uses.

The two-year rat study (Busey et al. 1967, 00001422) does not meet the Agency requirements for an oncogenicity test. The study does not contain information on incidence of neoplastic and non-neoplastic lesions observed in the study and it does not state the composition of the two chloronebs fed to the test animals. The Agency requires this additional information to evaluate the study. Registrants may cite this study as one of the two required oncogenicity studies provided that the registrants submits the missing lesion incidence and product composition data. The Agency will determine the validity of the study when the deficiencies are corrected.

Reproduction Testing

Teratology (163.83-3)

The minimum requirement for evaluating a pesticide for teratogenicity is testing in two mammalian species. It is required for both food and nonfood uses of chloroneb. No tests are available on chloroneb to assess teratogenic effects.

Reproduction (163.83-4)

The minimum requirement for measuring effects on reproduction is one test in the rat, lasting two generations. This is required for all food uses. No adequate studies assessing the effects of chloroneb on reproduction are available at this time. A rat reproduction study (Kundzin 1967, 00001423) containing summary data only is in Agency files. To satisfy this requirement, registrants may submit the referenced study (not the summary) provided it is supplemented by individual test animal data. The Agency will determine the validity of the study when the full data are submitted. available in detailed form.

Mutagenicity (163.84-1 through 4)

The following studies represent the minimum requirements for data on the potential heritable effects of chloroneb.

1. A mammalian *in vitro* point mutation test.
2. A sensitive sub-mammalian point mutation test. (Bacteria, fungi, insect)
3. A primary DNA damage test (i.e. sister chromatid exchange or unscheduled DNA synthesis).
4. A mammalian *in vitro* cytogenics test. If this test suggests a positive result, a dominant lethal or heritable translocation test may be required.

After results from these test systems and other toxicology disciplines have been considered, additional testing may be required to further characterize or quantify the potential genetic risks.

Although the Agency mutagenic testing requirements are not final, the standards for these tests should be based on the principles set forth there in FR 43, No. 163, Tuesday Augst 22, 1978. Protocols and choices of test systems should be accompanied by a scientific rationale. Substitution of test systems for those listed above will be considered after discussion with the Agency.

These requirements should be considered an interim guide and not final Agency policy. However, the Agency does not consider the above testing scheme to be a reasonable minimum requirement.

No adequate mutagenicity studies on chloroneb are available to the Agency.

Metabolism in Laboratory Animals (163.85-1)

A general metabolism study on chloroneb must be carried out to fulfill Agency requirements. A metabolism study is required because chronic studies are required for all food uses of chloroneb.

A metabolite of chloroneb, 2,5-dichloro-4-methoxyphenol (DCMP), has been identified in feces of dogs and in tissues and urine of rats and dogs fed chloroneb (Rhodes and Pease

1971, 05001159; du Pont 1967, 00001424). Both compounds showed a very low order of bioaccumulation in mammalian tissues.

Residues were measured in tissues and excreta of dogs and in tissues of rats fed chloroneb, as 65 or 75% wettable powders, in the diet for 2 years (du Pont 1967, 00001424). Liver, kidney, fat, muscle, spleen, testis, and brain were sampled from dogs and rats. In addition, blood and excreta were sampled from dogs. All samples were analyzed for content of chloroneb and its metabolite, DCMP, by the microcoulometric gas chromatographic method of Pease.

In dogs fed chloroneb for 2 years (at 7,500 ppm active ingredient for the last 19 weeks), up to 8 ppm chloroneb occurred in fat, and 2-6 ppm DCMP occurred in liver and kidney. In other tissues and in blood, respective contents of chloroneb and of DCMP did not exceed 1 or 0.4 ppm. Chloroneb was excreted in feces (2,300 ppm), and DCMP was excreted in urine (2,400 ppm) and in feces (560 ppm). In dogs fed 500 ppm for 2 years, chloroneb was found in fat (0.08 ppm), and its metabolite was found in liver and kidney (0.1-0.3 ppm). Dogs fed 100 ppm showed no chloroneb (less than 0.08 ppm) in tissues and DCMP (0.05 ppm) only in kidney. DCMP was excreted in urine and feces by dogs at both dietary levels, as was the parent compound in feces of mid-level dogs.

High-level (2,500-ppm) rats, similarly, showed more chloroneb (24 ppm) in fat and more metabolite in the kidneys (13 ppm) than in other tissues. This pattern held true in rats on 500 and 100 ppm chloroneb. Chloroneb occurred in fat (1.6 and 0.13 ppm), and the metabolite occurred in kidneys (5 and 1.4 ppm) of mid- and low-level rats, respectively. Otherwise, the compounds were generally undetectable (at detectability limits of 0.1 ppm and less) in other tissues of these rats.

Other unidentified chlorine-containing compounds were detected in minor amounts in a few samples from dogs and rats at the high dietary level only.

DCMP is a metabolite of chloroneb in cows, also. Gutenmann and Lisk (1969, 05001156) identified this compound in hydrolyzed samples of cow urine and in a 10,000-G supernatant fraction of beef liver incubated with chloroneb. No chloroneb (that is, less than 0.02 ppm) was found in the milk of either of two cows fed chloroneb for 30 days, one at 2 ppm and one at 50 ppm (Rhodes and Pease 1971, 05001159). DCMP was detected in the milk (0.2-0.4 ppm) of the cow fed the higher dose. After withdrawal of chloroneb from the diet, no metabolite (that is, less than 0.02 ppm) was detected in milk on the second day.

The extent of mammalian metabolism of chloroneb and the presence of other metabolites have not been investigated sufficiently. Single-dose testing on metabolism and pharmacokinetics of chloroneb must be carried out to comply with Agency requirements.

Clinical Trails

No clinical studies in humans have been conducted using chloroneb.

Emergency Treatment

No information on the prevention and treatment of chloroneb intoxication is available.

Toxicology - Wettable Powder Chloroneb

Toxicology Profile

No adequate tests are available to assess either the acute toxicity or possible skin or eye effects of wettable powder chloroneb formulations. Available data on wettable powder formulations containing 65 and 75% chloroneb are adequate to assess subchronic oral and subchronic dermal toxicity. Repeated application to human skin of wettable powder formulations are not expected t result in systemic effects, based on results of a subchronic dermal toxicity test in rabbits on the 75% formulation. See the Manufacturing-use Chloroneb Section of this chapter for a discussion of subchronic oral and dermal toxicity and chronic toxicity of chloroneb.

Data Gaps

Category of Test	Data Requirement	Guideline Number
Acute Oral	An acute oral toxicity test in male and female rats is required for each wettable powder.	163.81-1
Acute Dermal	An acute dermal toxicity study, preferably in the albino rabbit, is required for each wettable powder.	163.81-2
Acute Inhalation	An acute inhalation study in the rat is required for each wettable powder.	163.81-3

Primary Eye Irritation	A primary eye irritation test, preferably in the albino rabbit, is required for each wettable powder unless it has a pH of either 1-3 or 12-14 or if the product has been judged to be dermally corrosive. If so, it wil be regulated as a corrosive substance.	163.81-4
Primary Dermal Irritation	A primary dermal irritation test, preferably in the albino rabbit, is required for each wettable powder.	163.81-5
Skin Sensitization	A skin sensitization test in the guinea pig is required for each wettable powder formulation.	163.81-6

Human and Domestic Animal Hazard Assessment

All Formulations

Due to its appreciable vapor pressure, chloroneb in all formulations may be inhaled to a considerable extent by handlers or applicators (or domestic animals) at the application site. Whether it might contaminate drinking water has not been determined. Exposure to chloroneb-treated soil may involve contact with both chloroneb and its chlorophenol metabolites.

Wettable Powder Formulations (65%)

Considerable inhalation and skin absorption of chloroneb in a 65% wettable powder could occur. This is true, especially of grounds-keepers and golfers on golf fairways and greens. It could be true of applicators, especially if the formulation is used in excess of label directions (in severe fungal outbreaks). It might be spilled on the skin or in eyes of persons who dilute, tank-mix, or load spray equipment. Applicators could breathe spray droplets.

Test results suggest, indirectly, that a person (or domestic animal) should encounter only low systemic hazard from acute oral, acute dermal, or acute inhalation exposure to registered 65% wettable powders. However, further acute testing is needed on this and any other wettable powder formulations.

The potential for long-term repeated exposure to chloroneb -by any route- to harm human beings or domestic animals cannot be assessed fully because of its presently incomplete chemical and toxicologic characterization. Two-year dietary intake of pure chloroneb at 12.5 mg/kg body weight/day resulted in no observed harmful effect in rats and dogs. The test substance was first 98% chloroneb, then 90% administered as a 75% or 65% wettable powder. Increasing the intake by ten-fold or more suppressed growth and, variously, caused adverse effects on liver, kidney, stomach, or thyroid. At no level of intake did these animals accumulate significant amounts of chloroneb in body tissues examined, relative to degree of exposure, nor did they accumulate its chief known metabolite.

Adequate testing of technical chloroneb for teratogenic, carcinogenic and mutagenic potential; for effects on reproduction; and for mammalian metabolism/pharmcokinetics is not available. Such testing must not be done until the chemical composition of technical chloroneb is determined adequately as judged by the Agency.

Topical Discussions

For information concerning subchronic and chronic studies using a 65% and 75% wettable powder refer to the Manufacturing-use Chloroneb section of this chapter.

Topics

Acute Oral Toxicity
Acute Dermal Toxicity
Acute Inhalation Toxicity
Primary Eye Irritation
Primary Dermal Irritation
Skin Sensitization
Subchronic Dermal (21-Day) Toxicity

Acute Testing

Acute Oral Toxicity (163.81-1)

The minimum testing needed on acute oral toxicity is one test in the laboratory rat on each formulated wettable powder product.

No acute oral tests are available on wettable powders containing chloroneb.

Acute Dermal Toxicity (163.81-2)

The minimum testing needed on acute dermal toxicity is one test in the albino rabbit on each formulated wettable powder product.

No adequate test on a wettable powder formulation is available.

Acute Inhalation Toxicity (163.81-3)

An acute inhalation toxicity test is required on a wettable powder formulation if it causes a respirable vapor, or if 20% or more of the aerodynamic equivalent is composed of particles not larger than 10 microns.

Chloroneb has a relatively high vapor pressure and should provide a respirable vapor. Therefore, a test will be needed on each chloroneb wettable powder. No tests of acute inhalation toxicity are available on this formulation type.

Primary Eye Irritation (163.81-4)

The minimum testing needed to evaluate eye irritation potential is one test, in albino rabbits for each wettable powder formulated product. If the test substance has a pH of 1-3 or 12-14, however, it will be judged corrosive, and an eye irritation test is not needed. If the test substance is judged to be dermally corrosive, an eye irritation test is not needed.

No tests are available on wettable powder formulations containing chloroneb.

Primary Dermal Irritation

The minimum testing needed to evaluate dermal irritation potential is one test preferably in the albino rabbit, on each wettable powder formulated product.

No testing is available for wettable powder formulations containing chloroneb.

Skin Sensitization (163.81-6)

The minimum requirement for assessing skin sensitization is an intradermal test in one mammalian species, preferably the guinea pig, on each wettable powder product.

No adequate test for skin sensitization has been done on any chloroneb wettable powder product.

Subchronic Testing

Subchronic 21-Day Dermal Toxicity

The minimum requirement to assess subchronic 21-day dermal toxicity is one study, perferably in the albino rabbit, on each wettable powder formulation of chloroneb if any of its constituents is likely to increase skin absorption or to potentiate toxic and pharmacologic effects. The Agency will evaluate need for this study on a case-by-case basis.

No 21-day dermal study on a wettable powder formulation of chloroneb is available.

Toxicology - Granular

Toxicology Profile

Limited data are available on one granular formulation containing chloroneb as the only active ingredient. Both very low acute oral hazard and very low potential for primary dermal irritation are expected in humans for a granular formulation containing 6.75% chloroneb, based on the high acute oral LD_{50} in male rats (greater than 5 g/kg) and on the absence of dermal irritation on intact or abraded rabbit skin. Female rats, however, must be tested before a final assessment of acute oral hazard can be made on the 6.75% granular formulation. The acute oral or dermal hazard for other granular formulations cannot be assessed.

Testing that must be conducted on granular formulations, including additional tests required on the 6.75% formulation, is described in the section on Data Gaps.

Data Gaps

Category of Test	Data Requirement	Guideline Number
Acute Oral	An acute oral toxicity test in male and female rats is required for each granular, except that only females must be tested for one 6.75% granular formulation.	163.81-1
Acute Dermal	An acute dermal toxicity study, preferably in the albino rabbit, is required for each granular.	163.81-2

Acute Inhalation	An acute inhalation study in the rat is required for each granular.	163.81-3
Primary Eye Irritation	A primary eye irritation test in the albino rabbit is required for each granular unless it has a pH of either 1-3 or 12-14 or if the dermal substance is corrosive. If so, it will be regulated as a corrosive substance.	163.81-4
Primary Dermal Irritation	A primary dermal irritation test, preferably in the albino rabbit, is required for each granular formulation, except for one 6.75% granular formulation.	163.81-5
Skin Sensitization	A skin sensitization test in the guinea pig is required on each granular product.	163.81-6

Human and Domestic Animal Hazard Assessment

Granular Formulations

No significant exposure unique to granular formulations for humans is foreseen.

Based on test results, very low acute oral hazard and very low potential for primary skin irritations are expected in persons exposed to one 6.75% granular formulation, based on test results.

Further acute testing which is needed on this and other granular formulations is described in the preceding section, Data Gaps.

The potential for long-term repeated exposure to chloroneb -by any route- to harm human beings or domestic animals cannot be assessed fully because of its presently incomplete chemical and toxicologic characterization. Two-year dietary intake of pure chloroneb at 12.5 mg/kg body weight/day resulted in no observed harmful effect in rats and dogs. The test substance was first 98% chloroneb, then 90% administered as a 75% or 65% wettable powder. Increasing the intake by ten-fold or more suppressed growth and, variously, caused adverse effects on liver, kidney, stomach, or thyroid. At no level of intake did these animals accumulate significant amounts of chloroneb in body tissues examined, relative to degree of exposure, nor did they accumulate its chief known metabolite.

Adequate testing of technical chloroneb for tetratogenic, carcinogenic and mutagenic potential; for effects on reproduction; and for mammalian metabolism/pharmcokinetics is not available. Such testing must not be done until the chemical composition of technical chloroneb is determined adequately as judged by the Agency.

Topical Discussions

Acute Oral Toxicity
Acute Dermal Toxicity
Acute Inhalation Toxicity
Primary Eye Irritation
Primary Dermal Irritation
Skin Sensitization
Subchronic Dermal (21-Day) Toxicity

Acute Testing

Acute Oral Toxicity

The minimum testing needed on acute oral toxicity is one test in the laboratory rat on each formulated granular product.

One study is available on a granular formulation containing 6.75% chloroneb (WARF 1971, 00001495). The acute oral LD_{50} of this formulation exceeds 5 g/kg in male rats. At this level, no deaths occurred. Because only males were tested, the acute oral toxicity of this formulation cannot be adequately assessed. For males, the data are adequate to place 6.75% chloroneb in toxicity Category IV, indicating a very low acute oral hazard. To complete the assessment, testing must also be conducted in female rats.

Acute Dermal Toxicity

The minimum testing needed on acute dermal toxicity is one test, perferably in the albino rabbit on each formulated granular product.

No acute dermal tests are available on granular formulations containing chloroneb.

Acute Inhalation Toxicity

An acute inhalation toxicity test is required on a granular formulation if it causes a respirable vapor or if 20% or more of the aerodynamic equivalent is composed of particles not larger than 10 microns. Chloroneb has a relatively high vapor pressure and should provide a respirable vapor. Therefore, a test will be needed on each granular formulation of chloroneb. No tests of acute inhalation toxicity are available on this formulation type.

Primary Eye Irritation

The minimum testing needed to evaluate eye irritation potential is one test, in albino rabbits, on each granular formulated product. If the test substance has a pH of 1-3 or 12-14, however, it will be judged corrosive, and an eye irritation test is not needed. If the test substance is dermally corrosive, it will be judged corrosive to the eye, and an eye irritation test is not needed.

No test are available on granular formulations containing chloroneb.

Primary Dermal Irritation

The minimum testing needed to evaluate dermal irritation potential is one test preferably in the albino rabbit on each granular formulated product.

A granular formulation containing 6.75% chloroneb was not irritating to intact to abraded rabbit skin (WARF 1971, 00001495). No erythema or edema was noted at 24 or 72 hours. The study is adequate to place 6.75% chloroneb in Category IV, indicating a very low potential for dermal irritation.

Skin Sensitization

The minimum requirement for assessing dermal sensitization is an intradermal test in one mammalian species, perferably the guinea pig, on each granular formulation of chloroneb. None is available.

Subchronic Testing

Subchronic 21-Day Dermal Toxicity

The minimum requirement to assess subchronic 21-day dermal toxicity is one study, perferably in the albino rabbit, on each granular formulation of chloroneb if any of its constituents is likely to increase skin absorption or to potentiate toxic and pharmacologic effects. The Agency will evaluate need for this study on a case-by-cse basis.

No 21-day dermal study on a granular formulation of chloroneb is available.

Toxicology - Dust

Toxicology Profile

Since no testing is available on dust chloroneb, no summary can be made. The required tests are listed in the section on Data Gaps.

Data Gaps

Category of Test	Data Requirement	Guideline Number
Acute Oral	An acute oral toxicity test in male and female rats is required for each dust product.	163.81-1
Acute Dermal	An acute dermal toxicity study, preferably in the albino rabbit, is required for each dust product.	163.81-2
Acute Inhalation	An acute inhalation study in the rat is required for each dust product.	163.81-3
Primary Eye Irritation	A primary eye irritation test in the albino rabbit is required for each dust product unless it has a pH of either 1-3 or 12-14. or unless it has been judged dermally corrosive. If so, it will be regulated as a corrosive substance.	163.81-4
Primary Dermal Irritation	A primary dermal irritation test, preferably in the albino rabbit, is required for each dust product.	163.81-5
Skin Sensitization	A skin sensitization test is is required for each dust formulation.	163.81-6

Human and Domestic Animal Hazard Assessment

Dust Formulations

Contact with any dust formulation by inhalation or skin adsorption is possible.

No tests on a dust formulation are contained in Agency files. Therefore, the acute hazard of exposure to dust chloroneb cannot be assessed.

The potential for long-term repeated exposure to chloroneb -by any route- to harm human beings or domestic animals cannot be assessed fully because of its presently incomplete chemical and toxicologic characterization. Two-year dietary intake of pure chloroneb at 12.5 mg/kg body weight/day resulted in no observed harmful effect in rats and dogs. The test substance was first 98% chloroneb, then 90% administered as a 75% ir 65% wettable powder. Increasing the intake by ten-fold or more suppressed growth and, variously, caused adverse effects on liver, kidney, stomach, or thyroid. At no level of intake did these animals accumulate significant amounts of chloroneb in body tissues examined, relative to degree of exposure, nor did they accumulate its chief known metabolite.

Adequate testing of technical chloroneb for tetratogenic, carcinogenic and mutagenic potential; for effects on reproduction; and for mammalian metabolism/phamcokinetics is not available.

Topical Discussions

Topics

Acute Oral Toxicity
Acute Dermal Toxicity
Acute Inhalation Toxicity
Primary Eye Irritation
Primary Dermal Irritation
Skin Sensitization
Subchronic (21-day) Toxicity

Acute Testing

Acute Oral Toxicity

The minimum testing needed on acute oral toxicity is one test in the laboratory rat on each formulated dust product.

No tests on dust formulations containing chloroneb are available.

Acute Dermal Toxicity

The minimum testing needed on acute dermal toxicity is one test, preferably in the albino rabbit, on each formulated dust product.

No acute dermal tests are available on dust formulations containing chloroneb.

Acute Inhalation Toxicity

An acute inhalation toxicity test is required on a dust formulation if it causes a respirable vapor, or if 20% or more of the aerodynamic equivalent is composed of particles not larger than 10 microns. Chloroneb has a relatively high vapor pressure and should provide a respirable vapor. Therefore, a test will be needed on each chloroneb dust formulation. No tests of acute inhalation toxicity are available on this formulation type.

Primary Eye Irritation

The minimum testing needed to evaluate eye irritation potential is one test, in albino rabbits, on each formulated dust product. If the test substance has a pH of 1-3 or 12-14, however, it will be judged corrosive, and an eye irritation test is not needed. If the test substance has been judged dermally corrosive, the test substance will be judged to be corrosive to the eye and an eye irritation test is not needed.

No tests are available on granular formulations containing chloroneb.

Primary Dermal Irritation

The minimum testing needed to evaluate dermal irritation potential is one test, preferably in the albino rabbit, on each dust formulated product.

Testing on dust formulations containing chloroneb is not available.

Skin Sensitization

The minimum requirement for assessing dermal sensitization is an intradermal test in one mammalian species, preferably the guinea pig, on each dust formulation of chloroneb. None is available.

Subchronic Testing

Subchronic 21-Day Dermal Toxicity

The minimum requirement to assess subchronic 21-day dermal toxicity is one study, preferably in the albino rabbit, on each dust formulation of chloroneb if any of its constituents is likely to increase skin absorption or to potentiate toxic and pharmacologic effects. The Agency will evaluate need for this study on a case-by-case basis.

No 21-day dermal study on a dust formulation of chloroneb is available.

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VI. RESIDUE CHEMISTRY

Residue Chemistry - Manufacturing-Use Chloroneb

Residue Chemistry Profile

Chloroneb is a fungicide used to protect cotton, bean, soybean, and sugarbeet seedlings against a variety of diseases. For this use, the fungicide is applied either directly to seed or in-furrow at time of planting. Chloroneb is also used on ornamental turf grass to control blights.

Chloroneb has been shown by a variety of methods to be systemic in plants. The compound is taken up through the roots and distributed throughout the plants, concentrating most heavily in roots, lower stem, and cotyledons. There is little redistribution of residues in plants during maturation.

Chloroneb is extensively metabolized in plants to 2,5-dichloro-4-methoxyphenol, which is present in plant tissues as the free phenol and as a glucose conjugate. The phenol is metabolized to a small extent to 2,5-dichlorohydroquinone, which is, in turn, converted to 2,5-dichloroquinone.

In animals, metabolism of chloroneb also proceeds via 2,5-dichloro-4-methoxyphenol. Unidentified conjugates of the phenol have been found in urine and in milk of cows fed high dose of chloroneb.

The gas chromatographic method of Pease is capable of determining chloroneb, free 2,5-dichloro-4-methoxyphenol, and acid labile conjugates of the phenol. The method is suitable for obtaining data on residues in raw agricultural commodities and for tolerance enforcement. The method has been validated for use on snap beans, snap bean foliage, dried beans, peas, soybeans, cottonseed, sugarbeet roots , sugarbeet tops, meat, meat by-products, and milk. The sensitivity of the method for most commodities is 0.02 ppm.

Data on crops indicate that at present directed rates of applications, residues are generally higher in plants grown from seed treated in-furrow than in plants grown from seed directly treated with the fungicide. Residues in seeds of plants grown from chloroneb treated seed are ordinarily below detectable levels, however, residues in foliage of plants grown from treated seed are quite high soon after emergence, decreasing to low but detectable levels six weeks after emergence. Residues in mature plants consist principally of free conjugated 2,5-dichloro-4-methoxyphenol.

Residues were found in the kidney of a cow maintained on 2 ppm chloroneb and in milk of a cow maintained on 50 ppm chloroneb. The residue consisted of 2,5-dichloro-4-methoxyphenol probably as a conjugate.

Data Gaps

The following data are required to support the tolerances for chloroneb.

1) Data on the metabolism of chloroneb in food animals. Available data are qualitative, whereas quantitative as well as qualitative data on the disposition of chloroneb in food animals are required.

2) Data on residues in beans and bean vines (forage), soybeans and soybean vines (forage), cottonseed and cotton forage, and sugarbeets (roots and tops). Available data were not submitted in raw* form and, with the exception of the data on beans, were obtained on an inadequate number of samples.

3) Information on the storage of agricultural commodities between sampling and residue analysis. Data on storage conditions and on the stability of residues during sample storage are required. No data are available.

4) Data on residues in fractions of processed cottonseed, soybeans, and sugarbeets. No data are available. The data would not be required if residue data requested in raw agricultural commodities are low enough that residues in processed commodities would not likely exceed 0.1 ppm, the tolerance on the raw commodities. The Agency assumes a maximum concentration factor of 5 in processing cottonseed and soybeans to oil, and a factor of 20 in processing sugarbeets to dried pulp. Therefore, fractionation studies would not be required if residues on cottonseed and soybeans were less than .02 ppm (.1ppm/5), and residues on sugarbeets were less than .005 ppm (.1ppm/20).

5) Data on whether residues are transferred from items of animal feed to meat and milk. Available data were obtained on too few animals, and were not submitted in raw* form.

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* Raw data are data which are uncorrected for reagant blanks, untreated crop blanks, and recovery fortified samples.

Topical Discussions

Use Patterns and Restrictions

Chloroneb is a fungicide used alone or in combination with other fungicides to protect cotton, bean, soybean, and sugarbeet seedlings against damping off, blights, and other seedling diseases, especially those caused by species of *Pythium*, *Rhizoctonia*, and *Sclerotium*. The fungicide is applied directly to seed or applied to soil as an in-furrow treatment at planting. Chloroneb is also broadcast or sprayed on ornamental turfgrass, including golf greens and fairways, to control blights caused by *Pythium* and *Typhula* species.

Chloroneb is available as an wettable-use product in wettable powder, dust, and granular formulations containing 1.015% to 65% chloroneb.

Dust and granular formulations of chloroneb intended for use on seeds of agricultural crops contain a label recommendation that the products supplement standard fungicide seed treatments. The label on a wettable powder formulation intended for the same use indicates that the product may be used alone or in combination with standard seed treatments.

For use directly on seeds, dust and wettable powder formulations are applied once at the rates indicated below:

	LBS. CHLORONEB PER 100 LBS. OF SEED	
SEED	DUST	WETTABLE POWDER
BEAN	0.2	0.16
SOYBEAN	0.2	0.16
COTTON	0.5	0.24[a], 0.41[b]
SUGARBEET	-	0.24

a East of the Rocky Mountains.

b West of the Rocky Mountains.

For use as an in-furrow treatment, formulations are applied once at the following rates:

	LBS. CHLORONEB PER ACRE		
SEED	DUST	GRANULES	WETTABLE POWDER
BEAN	1.0	1.0	0.98
SOYBEAN	1.0	1.0	0.98
COTTON	1.0-2.0	1.0-2.0	1.3-1.95

For use on turfgrass, granular formulations are broadcast 0.17 - 0.37 lbs. of chloroneb per thousand square feet (7.4-16.1 lbs. per acre). Products are applied one to three times a year for control of gray snow mold (*Typhula* blight), or every five to ten days for control of *Pythium* blight. The only wettable powder formulation registered for use on turfgrass is sprayed at 0.16 lbs. per three to five gallons per thousand square feet every five to seven days to control *Pythium* blight. For the control of *Typhula* blight, it should be sprayed once at 0.24 to 0.37 lbs. per three to five gallons per thousand square feet.

Chloroneb formulations contain a number of label restrictions. Formulations intended for direct application to seeds have a label warning against use of treated seed for food, feed, or oil purposes. Labels on formulations intended for use on bean and soybean seed prohibit grazing of plants grown from treated seeds within 45 days of planting. Labels on formulations intended for use on ornamental turfgrass contain a restriction on grazing or feeding of clippings from treated areas to livestock.

With the exception of the use of turfgrass, the above uses of chloroneb are food uses and are expected to result in residues in human food and animal feed. The use on ornamental turfgrass does not constitute a food use, provided the label restriction stated above is followed.

Uptake, Distribution, and Metabolism in Plants

Whenever a pesticide is proposed for use on agricultural crops, the Agency requires data on the fate of the pesticide in plants. It has been demonstrated by a variety of methods that chloroneb is systemic in plants. Soybean seeds treated with chloroneb and subsequently germinated in vermiculite contained a water extractable residue toxic to *Rhizoctonia solani* (Thapliyal and Sinclair 1970, 05001302). In a similar study, soybean seedlings grown from seed dusted with 8 oz. chloroneb per 100 lbs. of seed were divided into roots, hypocotyls, cotyledons and leaves, and water soluble extracts of the plant parts prepared. Extracts of cotyledons were inhibitory to *R. solani* 14 days after planting (Thapliyal and Sinclair 1971, 05001304). Extracts of chickpea seedlings grown from chloroneb-treated seed, grown in chloroneb-treated soil, or treated by root immersion in chloroneb solution, were toxic to *Sclerotium rolfsii*. Fungitoxic residues persisted for nine days in seedlings started in treated soil following transplantation to chloroneb-free soil. Root extracts were more toxic than extracts prepared from shoots (Verma and Vyas 1976, 05001172).

Ring-labeled ^{14}C-chloroneb has been shown by radioautography to be taken up in cotton seedlings (Rhodes 19??b, 00002218; Kirk, Sinclair, and Lambremont 1969, 05001181), in soybean seedlings (Kharbanda 1971, GS0007-013), in snap beans (Rhodes 1968, 00001430), and in turfgrass (Vargas and Turgeon 1975, 05001134). Heavy labeling of roots and lower stems was consistently seen in these studies. Cotyledons were heavily labeled in cotton (Rhodes 19??b, 00002218) and bean (Rhodes 1968, 00001430) seedlings grown from seeds planted in ^{14}C-chloroneb treated soil. Cotyledons were much less heavily labeled in a five-day old cotton seedling exposed to a ^{14}C-chloroneb solution by root immersion (Kirk, Sinclair, and Lambremont 1969, 05001181). There was noticeable labeling of true leaves only in the bean and cotton plants grown from seed planted in treated soil (Rhodes 19??b, 00002218; Rhodes, 1968, 00001430).

Data obtained by analysis of ^{14}C-chloroneb treated plants with liquid scintillation techniques support the radioautography data. Five-day old bush bean (*Phaseolus vulgaris* seedlings treated by root immersion in ^{14}C-chloroneb solution for 48 hours were labeled throughout the plants with the highest concentration of label in the roots and lower stem (Thorn 1973, 05001297). Soybean seedlings grown from seed dusted with ^{14}C-chloroneb were most heavily labeled in the cotyledons with little radioactivity in roots, hypocotyls and true leaves. There was no difference in radiolabel distribution between seedlings analyzed nine and 14 days after planting (Thapliyal and Sinclair 1971, 05001304). Five to seven-day old soybean seedlings immersed in a ^{14}C-chloroneb solution tended to accumulate radioactivity in the lower stem, with lesser amounts in the cotyledons and very little radioactivity in the upper stems and true leaves. Roots were not analyzed (Kharbanda 1971, GS0007-013). There was little redistribution of radioactivity to upper parts of maturing soybeans exposed for one week during the seedling stage to ^{14}C-chloroneb. It was also demonstrated in the same study that ^{14}C-chloroneb applied to true leaves of soybeans migrated to other parts of the plant although the pattern of distribution was highly variable (Kharbanda, 1971, GS0007-013). In snap bean (Rhodes, 1968, 00001430, Rhodes, Pease, and Brantley, 1971, 05001158) and cotton (Rhodes, 19??b, 00002218; Rhodes, Pease, and Brantley 1971, 05001158) seedlings grown from ^{14}C-chloroneb treated seed, radioactive residues predominated in roots, lower stems, and cotyledons, with little radioactivity being found in upper stems (above the cotyledons) and true leaves. There was no redistribution of radioactivity to upper portions of either cotton or bean plants during maturation. The level of radioactivity in roots resulting from in-furrow seed treatment was considerably higher than the level resulting from direct application of the labeled fungicide to seeds in both cotton and beans (Rhodes 19??b, 00002218; Rhodes 1968, 00001430).

Some data on metabolism of chloroneb in plants are available. Extracts of hypocotyls from soybean seedlings immersed in ^{14}C-chloroneb solution contained a labeled compound that was shown by thin-layer chromatography to be more polar than chloroneb (Kharbanda 1971, GS0007-013). Snap beans grown in a greenhouse from seed treated in-furrow with ring-labeled ^{14}C-chloroneb at 1 lb. per 12,000 row feet, and harvested 12 days after planting, contained four degradation products of chloroneb (Rhodes 1968b, 00001407; Rhodes, Pease and Brantley 1971, 05001158). These compounds, comprising over 80% of the total ^{14}C-residue, were identified as chloroneb (50.6% of the labeled material), 2,5-dichloro-4-methoxyphenol (45.8%), 2,5-dichlorohydroquinone (0.6%), and 2,5-dichloroquinone (0.9%). An additional compound comprising 2.1% of the extractable residue was not identified. Identification of compounds was based on comparison of chromatographic mobility, infrared spectra, and mass spectra with reference standards (Rhodes 1968b, 00001407; Rhodes, Pease, and Brantley 1971, 05001158).

Cotton plants grown in a greenhouse from seeds treated with 0.92 lbs. of ring-labeled ^{14}C-chloroneb per 12,000 row feet, and extracted and analyzed in the same manner as the snap beans described above contained the four degration products of chloroneb in a pattern remarkably like that seen in beans (Rhodes, Pease, and Brantley 1971, 05001158). Of the total ^{14}C-residue, 84% could be extracted, of which 52.1% was chloroneb, 44.2% was 2,5-dichloro-4-methoxyphenol, 0.7% was 2,5-dichlorohydroquinone, 0.9% was 2,5-dichloroquinone, and 2.1% was unidentified (Rhodes, Pease, and Brantley 1971, 05001158).

The above studies show that the predominant residues from the use of chloroneb on plants are the parent compound and free 2,5-dichloro-4-methoxyphenol. A somewhat different picture is seen in bush beans (*P. vulgaris*) treated by root immersion in ring-labeled ^{14}C-chloroneb solution. Ethanol extracts of roots, combined hypocotyl and cotyledons, and combined epicotyl and leaves were analyzed by thin-layer chromatography and found to contain 35% - 76% chloroneb, 4% - 8% of the free phenol, and 21% - 57% of the glucoside conjugate of the phenol (Thorn 1973, 05001297). Traces of 2,5-dichlorohydroquinone were also reported. The identity of the glucoside was determined by comparison of the chromatographic mobility of the labeled metabolite with synthesized glucoside in three solvent systems, and by crystallization to constant specific radioactivity of a mixture of the labeled metabolite and unlabeled synthetic glucoside (Thorn 1973, 05001297).

The failure to observe the glucoside conjugate in significant amounts in the snap bean and cotton studies (Rhodes 1968b, 00001407; Rhodes, Pease, and Brantley 1971, 05001158) may be due to the extraction procedure in which the first step is a digestion of plant material in 5N phosphoric acid. The glucoside conjugate, if initially present, would be expected to hydrolyze during the digestion. In the bush bean study (Thorn 1973, 05001297), the plant tissues were extracted with 80% ethanol.

The metabolism of chloroneb in plants is adequately defined for the currently registered uses of chloroneb. Chloroneb is taken up by plants through roots and distributed throughout the plant concentrating primarily in roots, lower stem, and cotyledons. Chloroneb is extensively metabolized to 2,5-dichloro-4-methoxyphenol which is in turn metabolized to a small extent to 2,5-dichlorohydroquinone, and 2,5-dichloroquinone. Evidence from one study indicates that, in bush beans, the phenol is readily conjugated with glucose and that the free phenol is present at very low concentration in beans.

Metabolism of Chloroneb in Food Animals

When use of a pesticide on agricultural crops results in residues in items of animal feed, the Agency requires data on the fate of the pesticide in food animals. Data on metabolism of chloroneb in food animals are sparse. A cow maintained for 30 days on a diet containing 2 ppm chloroneb was found to have 0.05 ppm of 2,5-dichloro-4-methoxyphenol in its kidneys (du Pont 1967a, 00001431; Rhodes and Pease 1971, 05001159). Another cow maintained on a diet containing 50 ppm of chloroneb had measurable milk levels of the phenol throughout the feeding period, and levels of 14 ppm in urine seven days after chloroneb feeding began (du Pont 1967a, 00001431; Rhodes and Pease 1971, 05001159). The samples in these studies were analyzed by the method of Pease (see Analytical Method below) which involves digesting samples in 5N phosphoric acid. Conjugates of 2,5-dichloro-4-methoxyphenol would likely be hydrolyzed to the free phenol during the digestion. However, the milk samples from the cow maintained on 50 ppm chloroneb were also analyzed by an alternative method in which samples were extracted with an organic solvent at neutral pH (Rhodes 19 a, 00002214). It was found that the phenol could be detected in milk only after refluxing of the sample with hydrochloric acid, indicating that the phenol was originally present in the samples as an acid labile conjugate.

A cow maintained for four days on a diet containing 5 ppm chloroneb had detectable amounts of 2,5-dichloro-4-methoxyphenol in acid hydrolyzed urine but not in unhydrolyzed urine, indicating the presence of conjugated phenol. The amount of phenol in the urine accounted for 44% of the ingested dose, however, the remaining dose was unaccounted for. The formation of the phenol from chloroneb was demonstrated by use of an in vitro metabolizing system using a crude microsomal preparation from beef liver (Gutenmann and Lisk 1969, 05001156).

The data on metabolism of chloroneb in food animals are inadequate. The available data show only that chloroneb is metabolized to 2,5-dichloro-4-methoxyphenol and that the phenol may be conjugated in milk and in urine. There have been no studies to determine the quantitative disposition of administered chloroneb in food animals. (For metabolism in laboratory animals see the "Toxicology" chapter.)

Analytical Methods

The Agency requires the submission of, or reference to, validated analytical methods suitable for obtaining data on the nature and amount of pesticide residues resulting from proposed use. One method must be suitable for tolerance enforcement. The regulatory method for determination of a pesticide in raw agricultural commodities must be capable of measuring the total toxic residue derived from the pesticide. Metabolism data indicate that chloroneb, 2,5-dichloro-4-methoxyphenol, and conjugates of the latter compound comprise the bulk of the residue found in plants and animals as a result of chloroneb use.

The regulatory method for chloroneb in Vol. II of the Pesticide Analytical Manual is the method of Pease (Pease 1967, 00001429). In this method a sample of plant or animal tissue is mixed with 5N phosphoric acid and subjected to 12 hours of simultaneous steam distillation and hexane extraction by means of a Bleidner apparatus. The hexane extract is carefully concentrated to a small volume and aliquots are analyzed by microcoulometric gas chromatography (MCGC) with temperature programming. Concentrated hexane extracts of samples with high oil content are cleaned-up prior to analyses by partition into acetonitrile or by Florisil columm chromatography with ethyl acetate as column elutant. Acetonitrile and ethyl acetate extracts are carefully concentrated to a small volume before analysis by MCGC.

The method determines chloroneb and the phenolic metabolite separately. The compounds are steam distilled during the phosphoric acid digestion procedure, and are determined during a single MCGC run. Chloroneb and the phenol are well separated on the gas chromatographic column. Conjugates of the phenol would be expected to hydrolyze during the 12 hour distillation-extraction step and would be determined as free phenol.

Recovery studies utilizing the Pease method have been carried out on snap beans, snap bean foliage, dry green beans, peas, soybeans, cottonseed, sugarbeet roots, and sugarbeet tops (Pease 1967, 00001429). The average recovery of chloroneb from 40 samples fortified at 0.02 to 1.0 ppm was 95% and individual values varied from 77% to 114%. Average recovery of the phenol from 40 samples fortified at 0.02 to 3.1 ppm was 88% and values ranged from 71% to 110% (Pease 1967, 00001429).

Recovery studies have also been carried out in bovine tissues including muscle, subcutaneous fat, liver, kidney, whole milk, milk fractions (fat and aqueous), and urine (du Pont 1967a, 00001431). The overall average recovery of chloroneb from 19 samples fortified at 0.02 to 0.55 ppm was 89% and values varied between 69% to 109%. Average recovery of 2,5-dichloro-4-methoxyphenol from 21 samples fortified with 0.02 to 1.03 ppm was 80% and values ranged from 54% to 110%. Recovery of both compounds from urine tended to be low.

The sensitivity of the method is 0.02 ppm each for both chloroneb and the phenol metabolite (1 ppm in urine). The Pease method is adequate for enforcement provided that no new toxic metabolites of chloroneb are identified.

Residues in Plants

Whenever a pesticide is proposed for use on an agricultural crop, the Agency requires data on the nature and amount of residue on the crop resulting from the proposed use. Limited residue data have been obtained with a variety of chloroneb formulations and ring-labeled ^{14}C-chloroneb formulated as a 75% wettable powder. With one exception (discussed below) crops treated with unlabeled chloroneb formulations were analyzed for residues of chloroneb and 2,5-dichloro-4-methoxyphenol by the method of Pease (Pease 1967, 00001429). Samples with ^{14}C-residues were analyzed by combustion techniques and subsequent scintillation counting.

Cotton

Cotton plants grown in a greenhouse from seeds treated with the ^{14}C-chloroneb formulation at 6.75 oz. chloroneb per 100 lbs. of seeds contained 150 ppm of chloroneb equivalents one week after planting, 0.7 ppm after eight weeks, and 0.2 ppm at 16 weeks. Seeds from plants sampled at 16-20 weeks contained no detectable (<0.01) residues (Rhodes, 19??b, 00002218; Rhodes, Pease and Brantley, 1971, 05001158).

Cotton plants, greenhouse-grown from seeds planted in soil treated with the ^{14}C-chloroneb formulation to simulate a field application rate of 2 lbs. active per 12,000 row ft., contained 397 ppm of chloroneb equivalents one week after planting and 7 ppm after eight weeks. Seeds contained 0.04 ppm after 22 weeks (Rhodes 19??b, 00002218; Rhodes, Pease, and Brantley 1971, 05001158).

Cotton plants from seed field-treated with the ^{14}C-chloroneb formulation by in-furrow application of 2 lbs. per 12,000 row feet contained 0.23 ppm chloroneb equivalents in whole plants at maturity and 0.03 ppm in seeds (Rhodes, 19??b, 00002218; Rhodes, Pease, and Brantley, 1971, 05001158).

Residues were not detected (<0.01 ppm) in 11 cottonseed samples from plants grown from seeds treated by direct application of a 5% dust containing 0.5 to 1.0 lbs. of chloroneb per 100 lbs. of seeds (du Pont 1967c, 00001412; du Pont 1965, 00001434.). No residues were detected in two samples of cottonseed from plants grown from seeds treated by in-furrow application of a wettable powder containing 75% chloroneb at 1.5 or 2.25 lbs. of chloroneb per acre-row (du Pont 1967c, 0001412; du Pont 1965, 00001434). The 13 seed samples were from nine locations in four southern states and were obtained 123 to 169 days after treatment. Samples were analyzed by an earlier version of the Pease method in which the samples are digested in a strongly alkaline medium instead of in acid. Consequently, the earlier method does not determine the phenolic metabolite of chloroneb (du Pont 1965 00001434).

Additional cottonseed samples were analyzed by the Pease method. Three samples, two from Mississippi and one from California, were from plants grown from seeds receiving 0.5 lbs. of chloroneb (unspecified formulation) per 100 lbs. of seed. One sample from Texas was from a plant grown from seed treated in-furrow at 1.2 lbs. chloroneb (unspecified formulation) per acre. Plants were harvested 135 to 157 days after treatment. Residues of chloroneb and its metabolite could not be detected (<0.02 ppm), except for a sample from a plant grown from directly treated seeds that contained 0.03 ppm chloroneb (du Pont 1967c, 00001412).

There are no data on residues in cotton foliage from use of non-radiolabeled chloroneb formulations. There are no data on cottonseed fractions from processed cottonseed.

Snap beans and dried beans

Residues in snap bean plants grown in a greenhouse from seed treated with 3 oz. ^{14}C-chloroneb per 100 lbs. of seed were 127 ppm one week after planting and 2.6 ppm after five weeks. Residues in edible pods were 0.04 ppm five weeks after planting (Rhodes 1968, 00001430; Rhodes, Pease, and Brantley 1971, 05001158).

Snap bean plants grown in a greenhouse from seeds treated by simulated in-furrow application of the ^{14}C-chloroneb application at 2 lbs. chloroneb per 12,000 row feet contained 290 ppm of chloroneb equivalents one week after planting and 18 ppm after five weeks. Residues in pods were 0.48 ppm at four weeks and 1.5 ppm five weeks after planting (Rhodes 1968, 00001430; Rhodes, Pease, and Brantley 1971 05001158).

Bean plants grown in the field from seeds treated by in-furrow application of the radiolabeled chloroneb formulation at 2 lbs. chloroneb per 12,000 row feet contained 2.1 ppm residues in whole plants at maturity. Pods contained 0.08 ppm. Residues in whole plants field grown from seeds treated by direct application of the ^{14}C-chloroneb formulation at 2.6 oz. per lbs. of seeds were 0.32 ppm at maturity. Residues in pods were 0.003 ppm (Rhodes 1968, 00001430, Rhodes, Pease, and Brantley 1971, 05001158). It should be noted that edible pods from greenhouse grown bean plants grown from in-furrow treated seeds contained much higher residues (0.48, 1.5 ppm) than pods from field grown plants treated in the same manner (0.08 ppm). The greenhouse plants were pot grown and their roots were, therefore, confined to the chloroneb treated soil throughout maturation, whereas the roots of field treated plants could grow past the chloroneb treated zone.

In a field study carried out at 13 locations in nine geographically dispersed states, bean seed were treated with chloroneb (unspecified formulation) in a planter box at 16-36 oz. chloroneb per 100 lbs. of seed; in a seed treater at 4-10 oz. chloroneb per 100 lbs. of seed, or were sown in soil treated in-furrow with wettable powder, granular, or dust formulations of chloroneb at 0.5-6 lbs. chloroneb per acre-row. Plants were harvested 48-85 days (snap beans) or

84-117 days (dried beans) after treatment, and edible pods and vines were analyzed by the method of Pease (Pease, 1967, 00001429). Seventeen pod samples were analyzed, 14 of which contain no chloroneb above the method sensitivity (0.02 ppm), and the remaining three samples contained 0.02 to 0.04 ppm of chloroneb. Thirteen of the 17 pod samples contained no detectable metabolite (0.02 ppm) and the other four samples contained metabolite levels of 0.03, 0.04, 0.09, and 0.14 ppm. Fifteen of the 17 snap bean vine samples contained chloroneb at 0.03 ppm or less. The remaining two samples are reported as "<0.2 ppm". Nine of the vine samples contained metabolite levels of 0.03 ppm or less. The remaining eight samples contained levels of the phenol from 0.11 to 2.0 ppm. In general these latter values were associated with in-furrow application, although within this group of eight samples, there was little correlation between application rate and residue level. Four samples of dried shelled beans and their vines were analyzed by the Pease method, the beans containing no detectable chloroneb or metabolite, the vines containing no detectable chloroneb, and two of the four vine samples containing no detectable metabolite. The other two vine samples contained 0.26 and 0.31 ppm of the metabolite (du Pont 1967b, 00001412).

Soybeans

Soybean seeds were treated with chloroneb in a seed treater at 4 oz. active per 100 lbs., or were sown in soil treated with granular or wettable powder formulations of chloroneb at 1 lb. active per acre. Plant samples from five locations in four states were harvested 133 to 179 days after treatment and beans and vines separately analyzed for residues by the Pease method. Six samples of beans contained no detectable (<0.02 ppm) level of either chloroneb or its metabolite, 2,5-dichloro-4-methoxyphenol. A single vine sample contained no detectable (<0.04 ppm) residue of either chloroneb or the metabolite (du Pont 1967b, 00001412).

Sugarbeets

Seeds were treated with chloroneb (unspecified formulation) at 2 to 12 ounces per 100 lbs. of seed. Six plant samples from three states were harvested 131 to 309 days after treatment, and roots and tops were analyzed separately for chloroneb and its phenol metabolite by the Pease method (Pease 1967, 00001429). No sample contained detectable (0.02 ppm) levels of either chloroneb or its metabolite. There have been no data submitted on processed sugarbeet fractions.

Adequacy of the data on residues in plants

The residue data are inadequate. There were no raw data submitted with any study. Raw data are needed by Agency scientists to evaluate data reliability.

No data on the handling of samples between harvest and analysis were presented. The only information on this matter indicates that sugarbeets sampled between 10/13/65 and 10/20/66 (du Pont 1967b, 00001412) were analyzed between 1/4/67 and 6/2/67 (du Pont 1968a, 00003269). Data on the storage stability of pesticide residues on crops is particularly relevant to chloroneb because of its volatility and the volatility of its phenol metabolite.

For most field grown crops, an insufficient number of samples were analyzed. Six soybean samples were analyzed for residues, and only one soybean foliage sample. Six sugarbeet samples were analyzed for residues in roots and tops. There were 18 cotton seed samples analyzed; however, only five of these samples were analyzed by methods capable of detecting both chloroneb and 2,5-dichloro-4-methoxy-phenol, and only two of these five reflected in-furrow use, the treatment method resulting in highest residues. There was one cotton foliage sample analyzed.

There were 23 bean plants analyzed, pods (or dried beans) and foliage being analyzed separately. Of the 23 bean plant samples, 12 reflected direct seed treatment and 11 reflected in-furrow treatment. The number of bean plant samples is considered adequate.

There were no data on fractions of processed soybeans, cottonseed, or sugarbeets. These data are required whenever the possibility exists that residues may concentrate in a particular fraction of a processed commodity.

Residues in Animals

When use of a pesticide on agricultural crops results in residues in items of animal feed, the Agency requires data on whether residues are transferred to meat, milk, poultry, and eggs.

Residues in Meat and Milk

There are limited data available on residues in meat and milk. In one feeding study, three cows were maintained on diets containing 0, 2, and 50 ppm chloroneb administered in a 65% wettable powder formulation. The cow maintained on 2 ppm chloroneb was sacrificed after 30 days of feeding, and the cow fed 50 ppm chloroneb was switched to chloroneb-free rations after 30 days and sacrificed after an additional seven days, an unacceptable procedure for a feeding study. Milk collected during the feeding study, and muscle, fat, liver, and kidney obtained at sacrifice were analyzed for chloroneb and 2,5-dichloro-4-methoxyphenol by the method of Pease (Pease 1967, 00001429). Chloroneb per se was not detected in any sample (<0.02 ppm). The phenol was present at 0.05 ppm in kidney tissue of the cow fed 2 ppm, however, the phenol was not detected in tissues of the cow fed 50 ppm chloroneb and sacrificed after a seven day withdrawal period. The metabolite was not detected in milk of the cow at 2 ppm chloroneb, but was present at 0.3 to 0.4 ppm in milk from the cow fed 50 ppm chloroneb. The metabolite dropped to undetectable (<0.02 ppm) levels in milk two days after withdrawal of chloroneb treated rations (Rhodes and Pease 1971, 05001159; du Pont 1967a, 00001431). Fractionation of the phenol-containing milk revealed that the bulk of the residue was in the aqueous phase (du Pont 1967a, 00001431).

In another study, a cow was maintained for four days on a diet containing 5 ppm chloroneb administered as the pure compound. Milk collected during the study was analyzed by a gas chromatographic method with electron capture detection. Neither of the compounds was detected (0.02 ppm)(Gutenmann and Lisk 1969, 05001156). No tissues were analyzed for residues in the study, and the method may not have had the capability of detecting conjugates of the phenol metabolite.

There are no data on residues of chloroneb in poultry and eggs.

Adequacy of the Data

The data on residues of chloroneb in milk and meat are not adequate. Raw data were not included and thus cannot be evaluated by Agency scientists. In addition, an insufficient number of animals were studied. One cow fed 2 ppm chloroneb was examined for tissue residues while chloroneb feeding was in progress (Rhodes and Pease 1971, 05001159; du Pont 1967a, 00001431). Another cow, fed an exaggerated level of 50 ppm chloroneb, was shown to have no detectable (<0.02 ppm) tissue residues of either chloroneb or metabolite. However, the animal was not sacrificed until seven days after chloroneb treatment had ceased (Rhodes and Pease 1971, 05001159; du Pont 1967a, 00001431). Thus data on the two cows cannot be compared. Milk samples from three cows fed 2, 5, and 50 ppm were analyzed, but the method used for analysis of milk from the cow fed 5 ppm chloroneb may not have detected conjugates of the phenol (Gutenmann and Lisk 1969, 05001156), whereas another study indicates that a conjugate is the primary residue of chloroneb to be found in milk (Rhodes 19??a, 00002214).

Unpublished Agency guidelines require that feeding studies be conducted on a minimum of 4 groups of 3 animals per group. The groups are fed 0-, 1-, 3-, and 10- fold the amount of pesticide expected in the diet, were the feed item in question to contain the tolerance level of pesticide. Normally the Agency requires that the pesticide fed correspond to the "aged" residue, however, data show that chloroneb is metabolized similarly in plants and animals and thus the parent compound above may be fed.

Residue Chemistry - Formulated Chloroneb

Registration Requirements

There are no residue chemistry data required for the non-food use of chloroneb.

For future registration of a pesticide product for use on a food or feed crop not covered by this Standard, the Agency must be provided with a full range of data including a validated method for analysis of pesticide residues in or on the raw agricultural commodity, data on metabolism of the pesticide in plants and (when appropriate) in animals, and residue data reflecting the proposed use of the pesticide on the crop. As discussed in this Standard an analytical method suitable for obtaining chloroneb residue data and for tolerance enforcement is available. Registrants are therefore not required to provide a method.

Required Labeling - Wettable Powder

Labels on wettable powder chloroneb used for direct application to seed should contain a restriction against the use of treated seed for food, feed, or oil purposes. Wettable powder chloroneb intended for use on beans or soybeans should bear a label restriction against grazing of treated plants within 45 days of planting. Labels on wettable powder chloroneb intended for use on ornamental turf grass should contain a restriction against grazing or feeding of clippings from treated areas to livestock.

Granular

Granular chloroneb intended for use on beans or soybeans should bear a label restriction against grazing of treated plants within 45 days of planting. Labels on granular chloroneb intended for use on ornamental turf grass should contain a restriction against grazing or feeding of clippings from treated areas to livestock.

As gaps in the residue chemistry data base are filled, other label restrictions or warnings may become necessary.

Dust

Labels on dust chloroneb used for direct application to seed should contain a restriction against the use of treated seed for food, feed, or oil purposes. Dust chloroneb intended for use on beans or soybeans should bear a label restriction against grazing of treated plants within 45 days of planting.

As gaps in the residue chemistry data base are filled, other label restrictions or warnings may become necessary.

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00001429	Pease, H.L. (1967) Determination of residues of Chloroneb and a metabolite by microcoulometric gas chromatography. Journal of Agricultural and Food Chemistry 15(5):917-919. Undated method. (Also In unpublished submission received Oct 16, 1967 under 8F0657; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:092951-G)

-MRID	CITATION
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05001302	Thapliyal, P.N., Sinclair, J.B. (1970) Uptake of three systemic fungicides by germinating soybean seed. Phytopathology 60(9):1373-1375
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VII. ECOLOGICAL EFFECTS

Ecological Effects - Manufacturing-Use Chloroneb

Ecological Effects Profile

Currently available data indicate that manufacturing-use chloroneb is practically non-toxic to most terrestrial wildlife. Manufacturing-use chloroneb is moderately toxic to aquatic organisms.

Manufacturing-use chloroneb appears to be relatively non-toxic to birds. Dietary studies on both the bobwhite quail and mallard duck yielded LC_{50} values of greater than 5000 ppm. An acute oral study for birds is not available.

The available aquatic toxicity data suggest that manufacturing-use chloroneb is moderately toxic to fish and aquatic invertebrates. The 48 hour LC_{50} for an aquatic invertebrate (Daphnia) was approximately 6 ppm. The 96 hour LC_{50} for a coldwater fish (rainbow trout) was 3.7 ppm. The test for a warmwater fish is not available.

Data Gaps

The following fish and wildlife studies testing the effects of technical chloroneb are required.

	Guidelines Section
a. An avian single-dose oral LD_{50} on either the bobwhite quail or the mallard duck.	163.71-1
b. A 96 hour acute LC_{50} to a species of warmwater fish (preferably the bluegill sunfish).	163.72-1

Considering use patterns and environmental fate information, a "second tier" study may be required. Section 163.72-4 of the June 10, 1978 proposed Guidelines lists the requirements for an embryolarval and/or an aquatic invertebrate life cycle test. The use information and available half-life data suggest that chronic levels of the chemical could be available to the aquatic environment. If the leaching data indicate chemical movement, one or both of these tests will be necessary. Whether or not one or both of these tests will be required will depend on environmental fate and toxicity data. A determination will be made after the Agency receives the data.

Topical Discussions

Corresponding to each of the Topical Discussions listed below is the number of the section(s) in the 'Proposed Guidelines' of July 10, 1978. (43 FR No. 132,29696) which explain(s) the minimum data that the Agency require to adequately assess chloroneb's Ecological Effects. Where no section number is listed, a minimum requirement has not been set for such information.

	Guidelines Section
Birds	163.71-1, 163.71-2
Fish	163.72-1
Aquatic Invertebrates	163.72-2

Freshwater Fish

The minimum data required for establishing the acute toxicity of manufacturing-use chloroneb for fish is a determination of the 96-hour LC_{50} for a coldwater species (preferably rainbow trout) and a warmwater species (preferably bluegill sunfish).

Acceptable data are available on the acute toxicity of technical chloroneb to rainbow trout (Salmo gairdneri). Zihal (1979) determined the 96-hour LC_{50} of 90% technical chloroneb at 3.7 ppm. This study characterizes chloroneb as moderately toxic to coldwater fish, and satisfies the requirement for a coldwater fish study.

Trivits (1979) provides supplemental information for warmwater fish (bluegill sunfish, Lepomis macrochirus). This study does not fulfill the guideline requirements for toxicity studies for warmwater fish. It does, however, provide sufficient information to characterize chloroneb as at least moderately toxic to warmwater fish. Because no studies were available that satisfy the guideline requirements, a data gap exists for warmwater fish.

Birds

Birds may be exposed to pesticides by feeding on contaminated plants or insects, by dermal contact and/or inhalation when close to outdoor sprays and dust. To assess the impact of a pesticide on birds, the Agency requires certain avian toxicity tests to support the registration of pesticides.

A determination of the avian acute single-dose oral LD_{50} is required to support the registration of every manufacturing-use product and formulated product for outdoor application. Acute testing must be performed on one avian species, either a wild waterfowl or an upland gamebird. (The species tested shall be the same as one of the two species used for the avian dietary tests.) Information regarding the acute toxicity of chloroneb to birds is not available; as such a data gap exists.

A determination of the subacute dietary LC_{50} (5-day dietary exposure) is also required to support the registration of all manufacturing-use products and all formulated products intended for outdoor application. These studies should be conducted using the technical material in the diet of an upland gamebird and a wild waterfowl.

Acceptable data are available on the effects of chloroneb in the diet of mallard ducks (Anas platyrhynchos) and bobwhite quail (Colinis virginianus). The information is summarized in the following table:

TABLE: DIETARY TOXICITY OF CHLORONEB TO BIRDS

SPECIES	FORMULATION	8-DAY DIETARY	REFERENCE
Mallard duck	90% Technical	>5000 ppm	Hinkle 1979 (GS00007-001)
Bobwhite quail	90% Technical	>5000 ppm	Hinkle 1979 (GS00007-002)

These studies characterize chloroneb's dietary toxicity as practically non-toxic to upland game birds and wild waterfowl. The dietary study requirements for birds have been satisfied.

A decision to require chronic toxicity data (reproductive or simulated and actual field tests), must await further information.

Aquatic Invertebrates

A determination of the 48-hour EC_{50} or LC_{50} for an aquatic invertebrate species is required to support the registration of all manufacturing-use products and for all formulated products intended for outdoor application.

A 48-hour toxicity test (Goodman 1979) was performed using 90% technical chloroneb on the water flea, Daphnia magna. The reported 48-hour LC_{50} was 6.19 ppm. This study characterizes chloroneb as moderately toxic to freshwater aquatic invertebrates. The guidelines requirement for the acute toxicity to freshwater aquatic invertebrates has been satisfied.

The decision to require life-cycle or other tests on aquatic invertebrates will depend on, but not be limited to, a consideration of chloroneb's use patterns, persistence, bioaccumulation, mobility and degradation rates. Sufficient information on the environmental fate of chloroneb is not available at this time.

Wettable Powder - Ecological Effects Profile

The toxicity of wettable powder chloroneb to wildlife may be estimated from tests on the manufacturing-use chemical.

Topical Discussions

See the Manufacturing-Use Chloroneb section of this chapter for the ecological effects requirements to support the registration of chloroneb formulated products.

The use patterns and formulations currently under consideration do not indicate the need for acute fish and wildlife tests using the formulated products. The toxicity of the various formulations and the subsequent hazard to wildlife can be estimated by using the toxicity data provided by tests of the technical chemical.

Ecological Effects Profile - Granular Chloroneb

The toxicity of granular chloroneb to wildlife may be estimated from tests on the technical chemical.

Topical Discussions

See the Manufacturing-Use Chloroneb section of this chapter for the ecological effects requirements to support the registration of chloroneb formulated products.

Fish and Wildlife

The use patterns and formulations currently under consideration do not indicate the need for acute fish and wildlife tests using the formulated products. The toxicity of the various formulations and the subsequent hazard to wildlife can be estimated by using the toxicity data provided by tests of the technical chemical.

Terrestrial Plants

The only available study (Scott 1971; 00001496) indicates that granular chloroneb has no phytotoxic effects on host grasses at the highest level tested. The no effect level for bentgrass (4.6, 9, or 12% granular formulation) was 58.5 pounds a.i. per acre. For Kentucky blue grass and perrenial ryegrass, the no effect level was 9.8 pounds a.i. per acre for 4.6, 9, or 12% granular formulations. This type of data is not, at present, required for registration.

Ecological Effects - Dust Chloroneb

The toxicity of dust chloroneb to wildlife may be estimated from tests on the technical chemical.

Topical Discussions

See the Manufacturing-Use Chloroneb section of this chapter for the ecological effects requirements to support the registration of chloroneb formulated products.

The use patterns and formulations currently under consideration do not indicate the need for acute fish and wildlife tests using the formulated products. The toxicity of the various formulations and the subsequent hazard to wildlife can be estimated by using the toxicity data provided by tests of the technical chemical.

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GS0007-002	Hinkle, S. (1979a) Avian Dietary Toxicity (LC_{50}) Study in Bobwhite Quail Project No. 1 201-528. (Unpublished study received Dec. 13, 1979 under 352-386; prepared by Hazleton Laboratories, Inc., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:241500)
GS0007-001	Hinkle, S. (1979b) Avian Dietary Toxicity (LC_{50}) in Mallard Ducks Project No. 201-527. (Unpublished study received Dec. 13, 1979 under 352-386; prepared by Hazleton Laboratories, Inc., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:241500)
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GUIDE TO USE OF THIS BIBLIOGRAPHY

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into 3 sections: (1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the standard, (2) citations examined and judged to be inappropriate for use in developing the standard, and (3) standard reference material. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, an eight-digit numeric identifier. This number is unique to the citations, and should be called the "Master Record Identifier", or "MRID". It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submissin. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever the Agency could confidently identify one, we have chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

   b. Document Date. When the data appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title. This is the third element in the citation. In some cases it has been necessary for out bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

   d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

      (1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission.

      (2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental perimt number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parentheseis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within acessin number 123456, the first study would be 123456-A; the second, 123456-B; the 26, 123456-Z; and the 27th, 123456-AA.

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